



HOUSEKEEPING:

Q&A: Please submit your questions in the Q&A. We have team members monitoring the Q&A and they will respond in real-time or during the Q&A session. If we are unable to answer questions during the webinar, we will follow up individually after the webinar.

Chat: Please use the chat function to provide general comments.

Webinar Recording: A recording of this webinar and the slides will be shared on CHAI's website.

Hepatitis C Market Intelligence Webinar

January 24th, 2024

HCV infection remains a major cause of liver disease globally, with significant testing and treatment gaps globally



58M

People living with chronic HCV as of 2019

290k

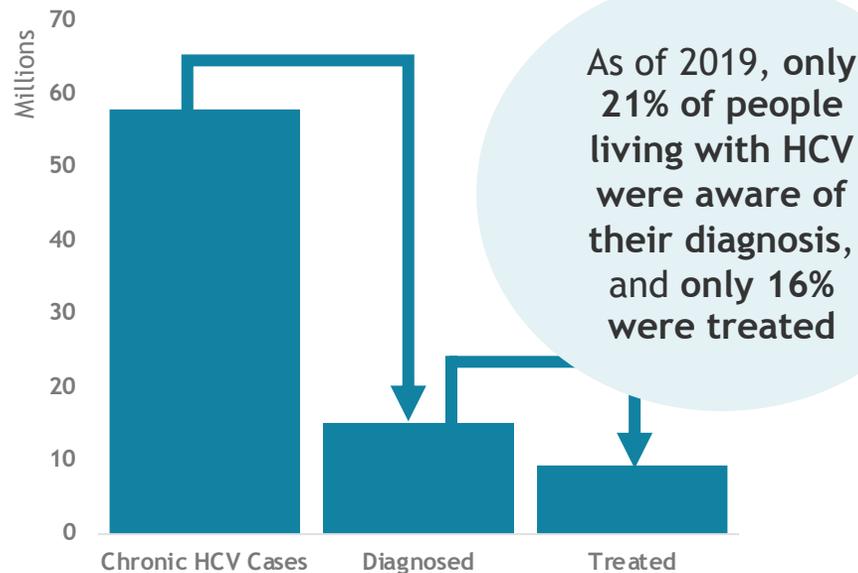
HCV-related deaths, mostly from cirrhosis and hepatocellular carcinoma

1.5M

New infections per year

3.2M

Adolescents and children living with chronic HCV



Barriers to HCV Elimination in LMICs

- ❖ Inadequate healthcare infrastructure
- ❖ Lack of resources and financial commitment from national governments and donors
- ❖ Low patient demand and awareness

Through political will, financing, and affordable commodities hepatitis programs can be more accessible and **pave the way towards global elimination.**

Sharing market intelligence can enable countries to advocate and secure better pricing for key diagnostics and drugs



CHAI HCV and HBV Market Intelligence Reports

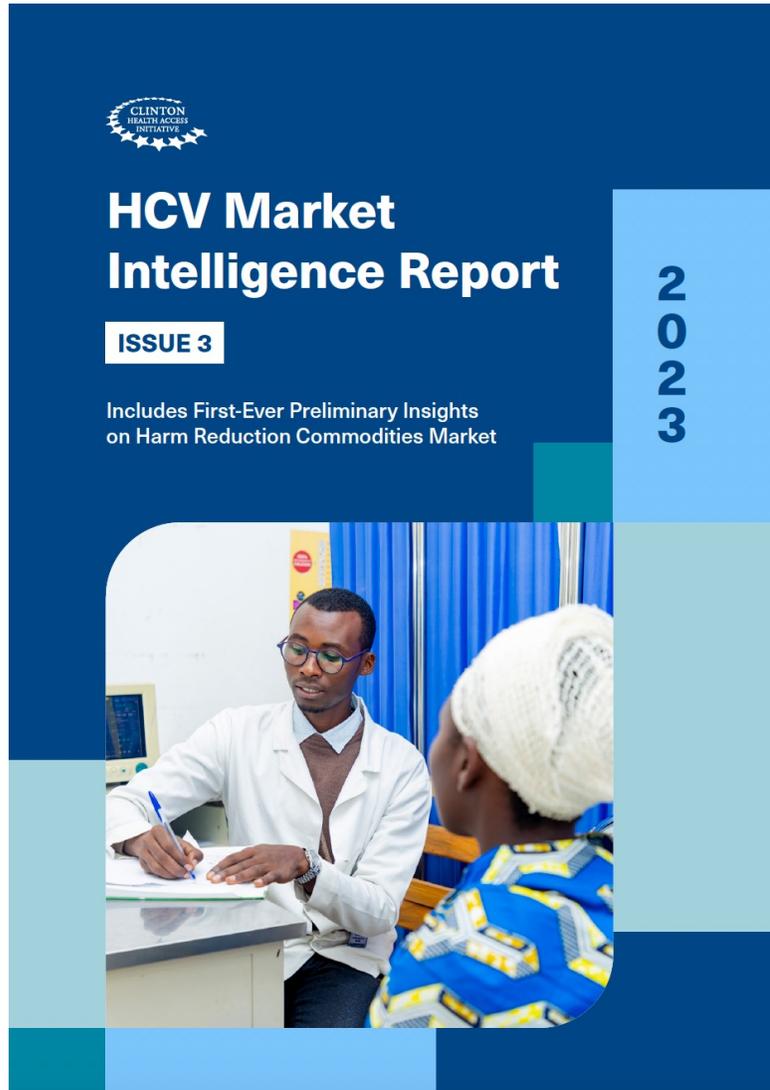
- Published two editions of market intelligence reports in 2020 and 2021
- In July 2022, CHAI published the **HCV Market Memo 2022**
- In December 2022, CHAI published the **HBV Market Report 2022**



OBJECTIVES

- 1** Build market transparency to ensure that high-burden LMICs have visibility into high-quality products at affordable prices
- 2** Showcase key drivers and barriers to scale diagnostic and treatment commodities
- 3** Highlight emerging market trends and innovations that have can significantly improve care for patients

3rd Edition of the HCV Market Report covers latest trends in the HCV diagnostics, treatment, and harm reduction markets



KEY TOPICS COVERED

- Strategies to achieve sustainable and affordable access to HCV diagnostics and treatment
- Supply landscape for HCV diagnostics and treatment
- Pricing trends for liver function tests, rapid diagnostic tests (RDT), viral load (VL), and DAAs
- Procurement volume trends for HCV RDTs and lab-based immunoassays, HCV viral load and DAAs
- Emerging diagnostic innovations
- Preliminary insights into market for harm reduction commodities

Webinar Agenda

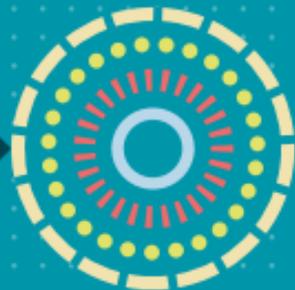
Opening Remarks		
Welcome Remarks & Introduction	Oriel Fernandes, Senior Director, Hepatitis Program (CHAI)	8 mins
Achieving HCV 2030 Elimination Goals	Meg Doherty, Director, Global HIV, Hepatitis and STI Programmes (WHO)	10 mins
HCV Market Report Highlights		
HCV Diagnostics Highlights	Robia Islam, Senior Associate, Global Diagnostics Team, Hepatitis (CHAI)	10 mins
HCV Treatment Highlights	Navya Sharma, Senior Analyst (CHAI)	10 mins
Harm Reduction Highlights	Navya Sharma, Senior Analyst (CHAI), Umesh Chawla, Associate Director, Hepatitis Program (CHAI)	10 mins
Market Impact Perspectives		
Country Perspective: Nigeria	Chukwuemeka Agwuocha, Program Manager, Hepatitis/COVID-19 Therapeutics (CHAI) Olayinka Adisa, Senior Analyst, Health Systems Strengthening/Access (CHAI)	5 mins
Community Perspective: HCV, Harm Reduction	Annie Madden, Project Lead (INPUD)	5 mins
Donor Perspective: Global Fund	Shaun McGovern, Advisor HIV Product Introduction (Global Fund)	5 mins
Discussion & Closing Remarks		
Q&A	Ritubhan Gautam, Manager, Global Markets Team (CHAI) Umesh Chawla, Associate Director, Hepatitis Program (CHAI)	15 mins
Closing Remarks	Oriel Fernandes, Senior Director, Hepatitis Program (CHAI)	5 mins



World Health
Organization

Achieving HCV (& HBV) 2030 Elimination Goals: WHO Perspective

Meg Doherty, MD, MPH, PHD
Director Global HIV, Hepatitis and STI Programmes
World Health Organization HQ
24 January 2024



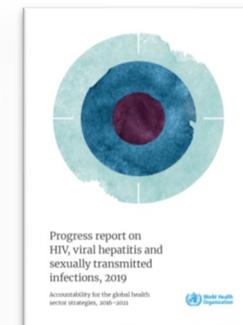
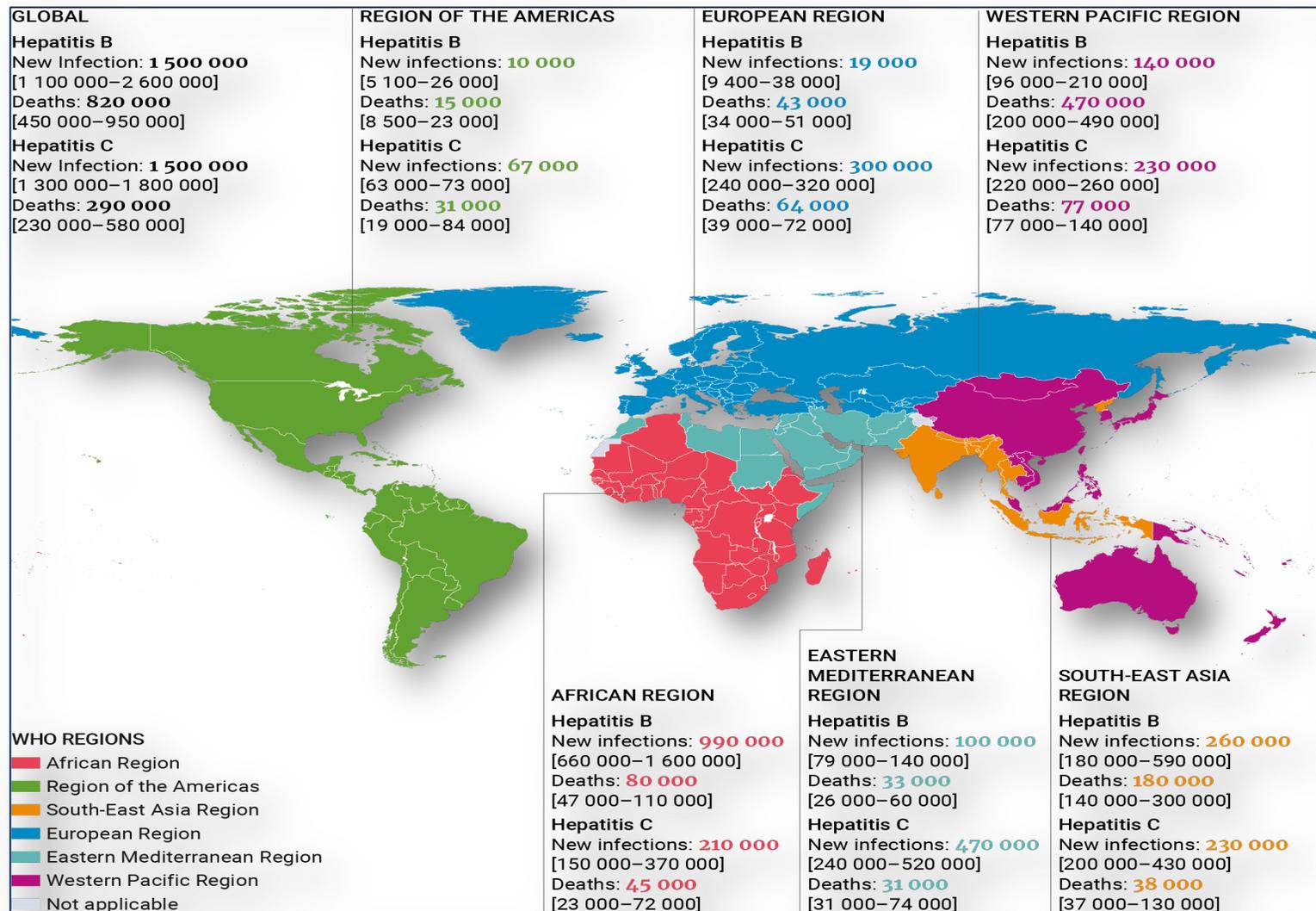
Ending epidemics
in a new global
health era

Hepatitis B and C burden, incidence and mortality by WHO region (2021 WHO Global progress report)

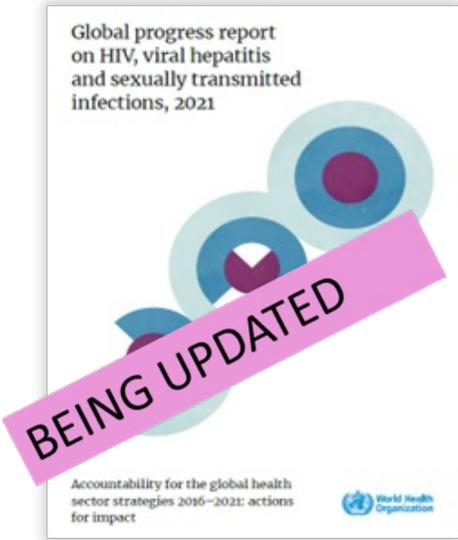
Global Burden
Hepatitis B - 296 m
Hepatitis C - 58 m

Viral Hepatitis
New data on incidence, prevalence

- **3.0 million** new HCV & HBV infections
- **1.1 million** HCV & HBV deaths with initial signs of HCV declines (290,000 deaths)
- **Achieved <5 yr HepB** prevalence SDG 2020 targets and GHSS goals



WHO Global Progress report (2016-2021)



Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021

BEING UPDATED

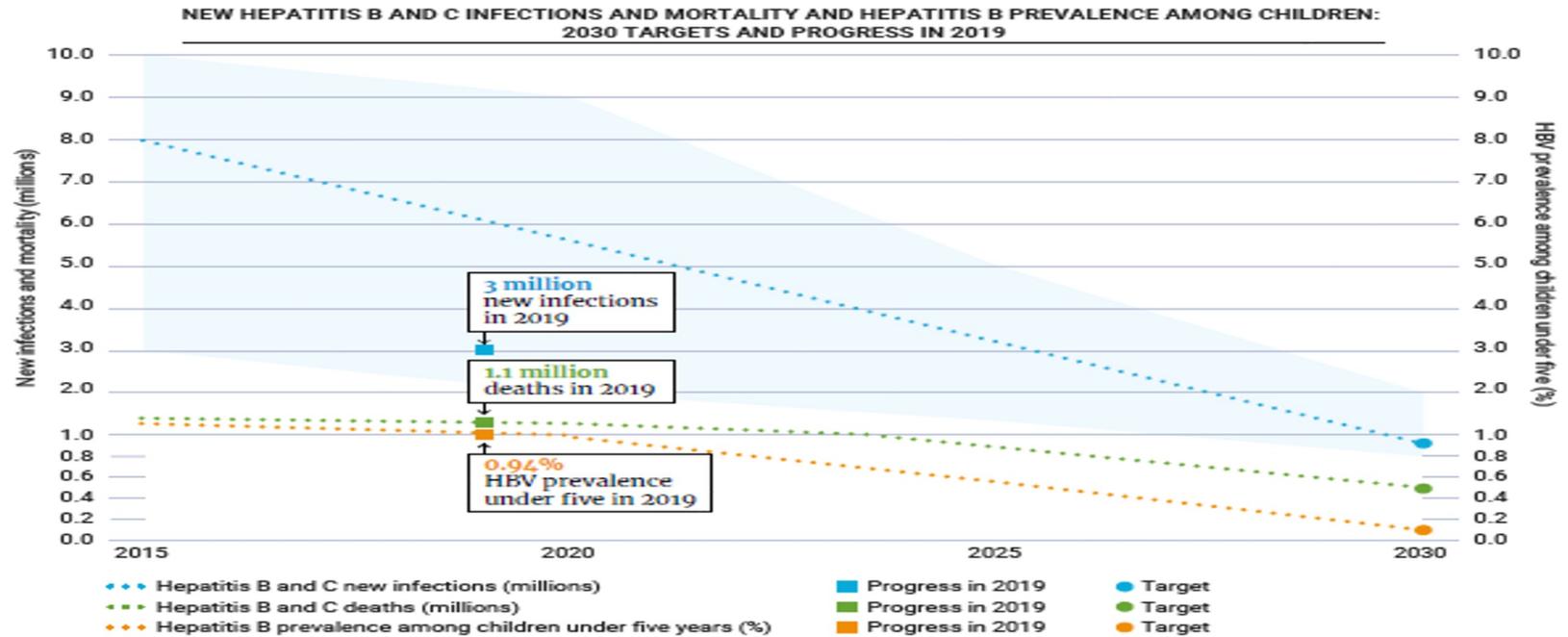
Accountability for the global health sector strategies 2016-2021: actions for impact



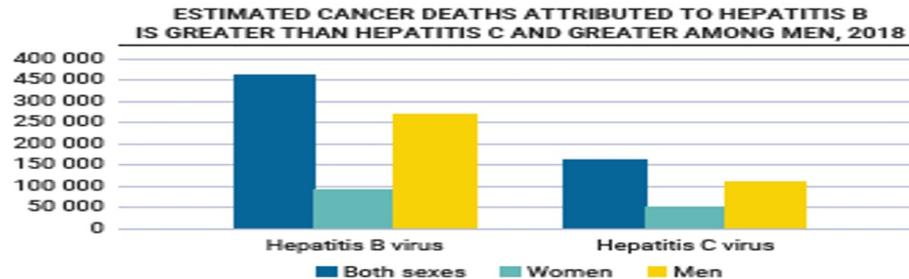
Coming soon



Fig. 18. New hepatitis B and C infections and mortality, hepatitis B prevalence among children and estimated cancer deaths attributable to hepatitis B



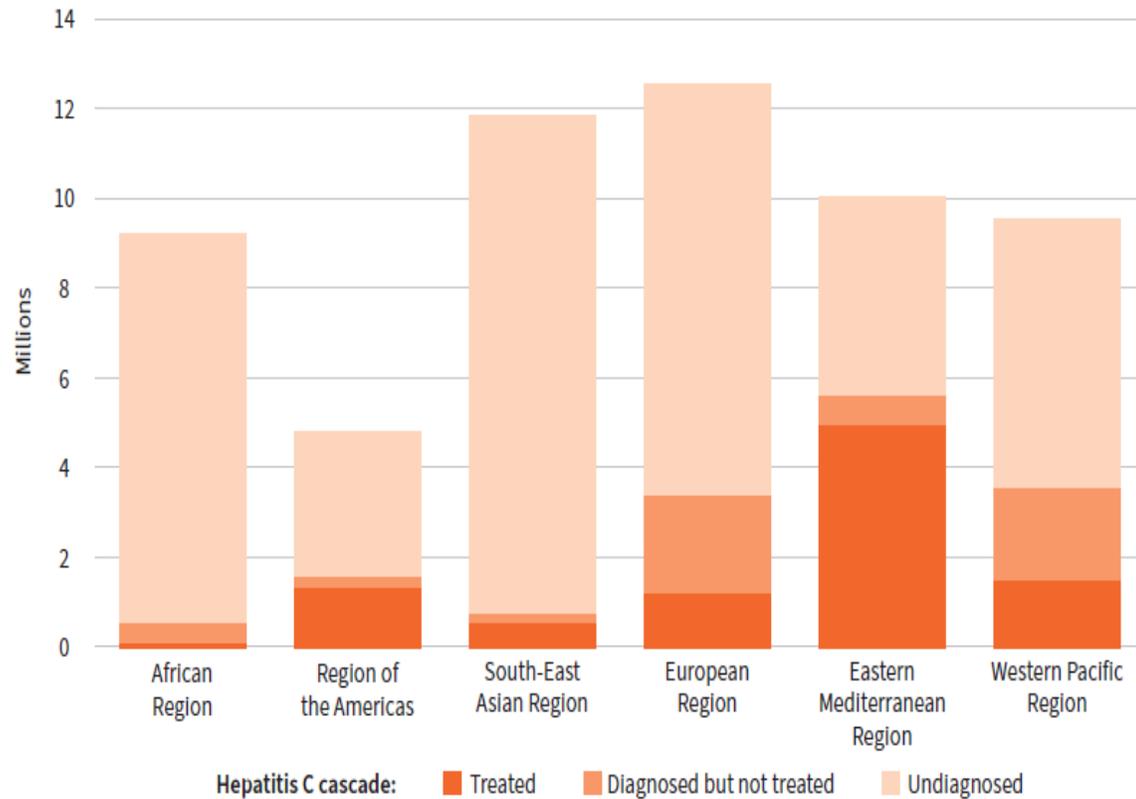
Source: WHO, 2021.



Source: International Agency for Research on Cancer and WHO, Global burden of cancer attributable to infections in 2018.

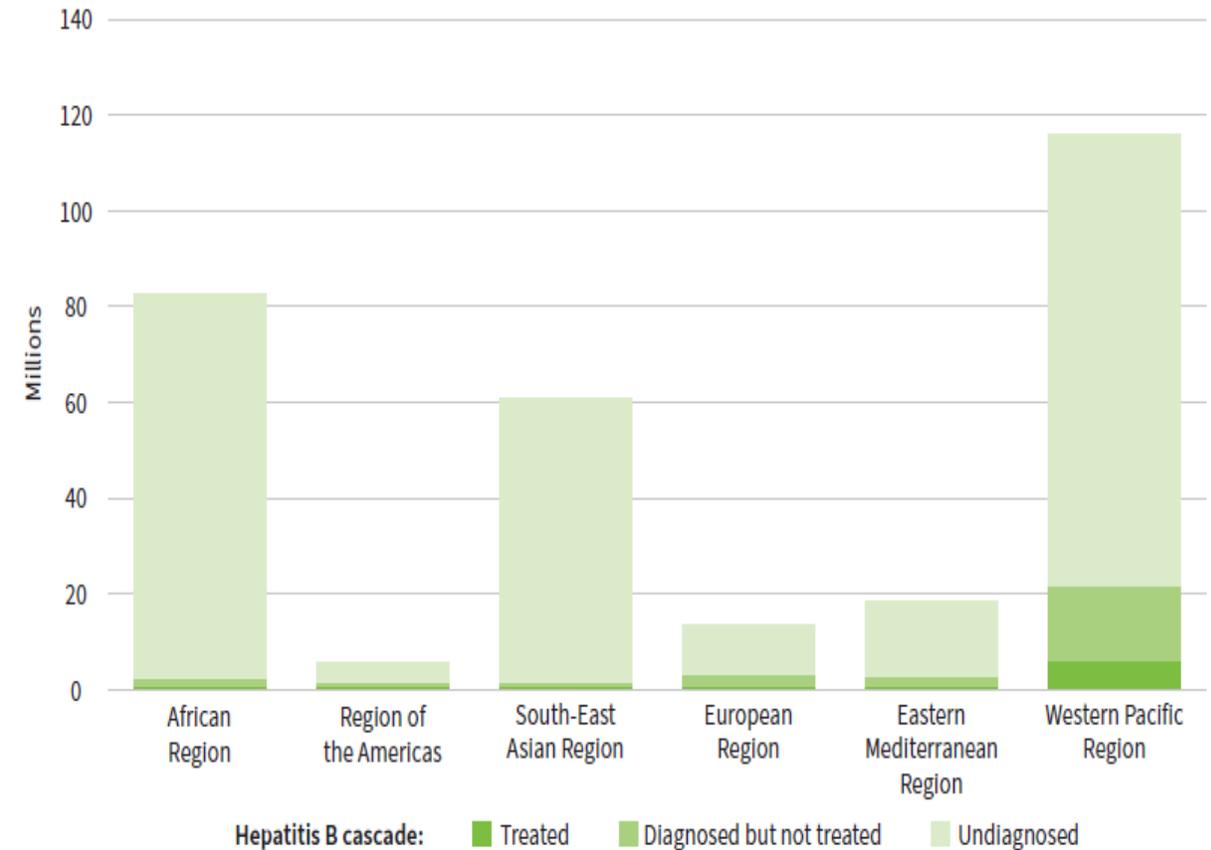
HBV & HCV Cascade of care - major gaps in testing and treatment on the path towards public health elimination

Fig. 2. Cascades of diagnosis and treatment for hepatitis C by WHO region

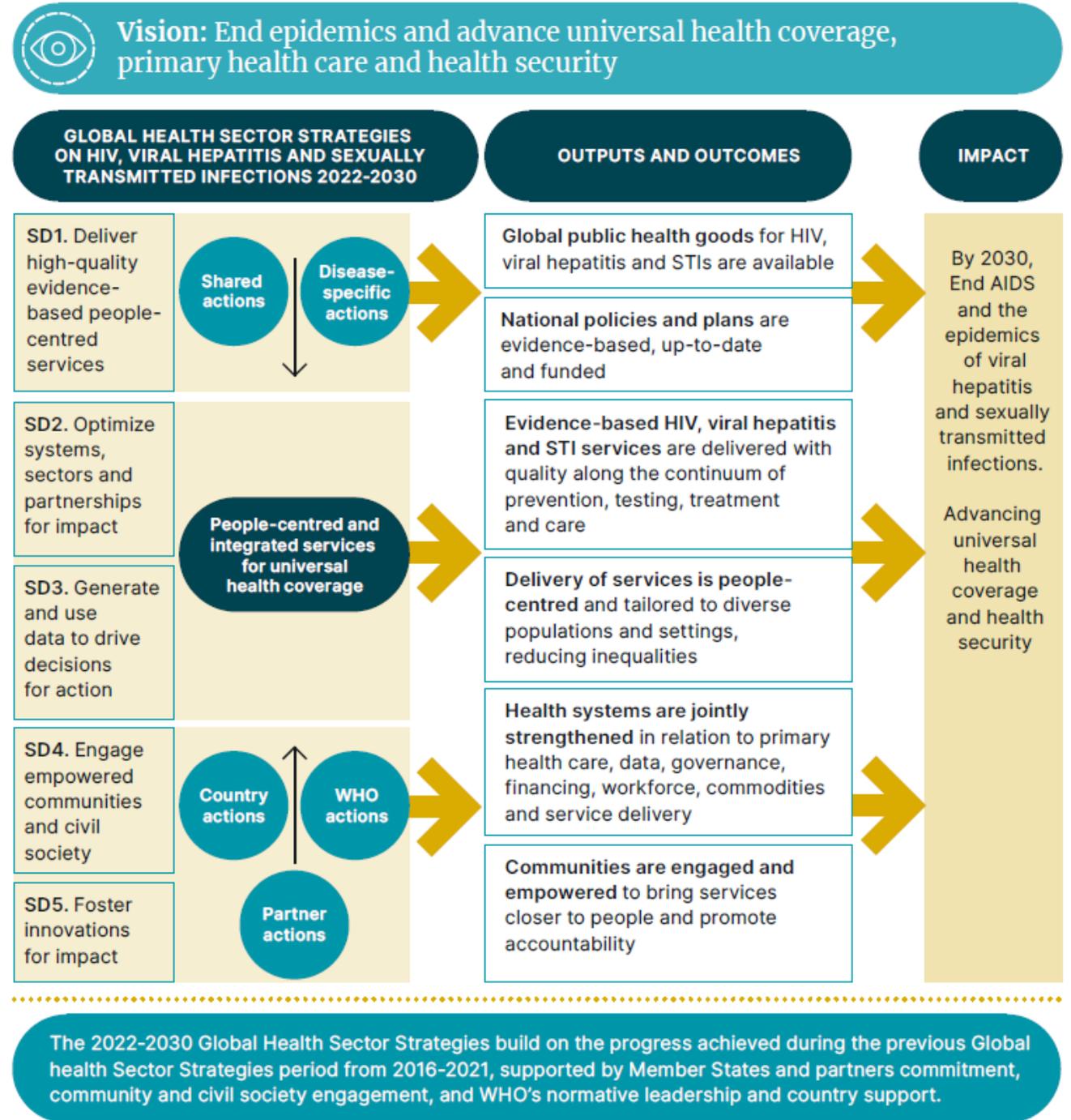
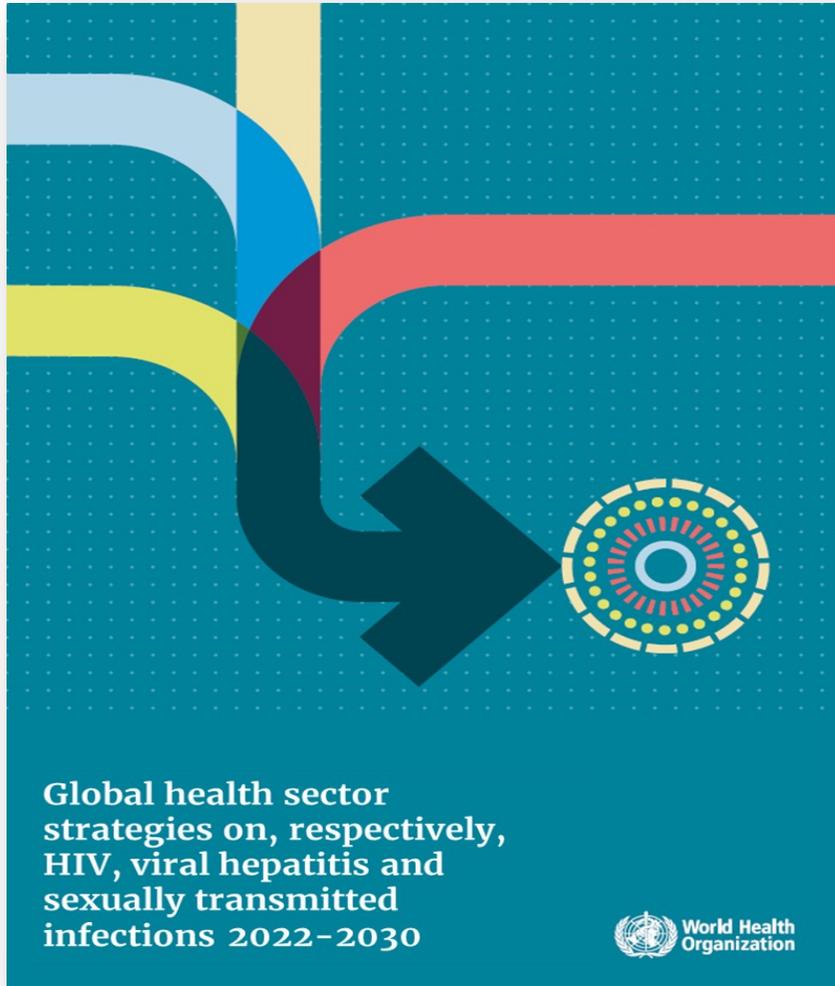


Source: Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016–2021: actions for impact (2).

Fig. 1. Cascades of diagnosis and treatment for hepatitis B by WHO region



The VISION: Reaching elimination of viral hepatitis B & C by 2030 by implementing the Strategic Directions of the GHSS



Global targets for elimination – including absolute targets for elimination



Impact target: Burden of infection-prevalence, incidence, mortality.

Coverage targets: HBV&HCV Cascade of diagnosis, care and cure

Milestones: Policies & guideline uptake, integration, **drug and diagnostics access**

Table 5.1. Impact and coverage indicators, targets and milestones for viral hepatitis by 2030

	Indicator	Baseline – 2020 ^a	Targets – 2025	Targets – 2030
Impact	Hepatitis B surface antigen (HBsAg) prevalence among children younger than 5 years old ^b	0.94%	0.5%	0.1%
	Number of new hepatitis B infections per year	1.5 million new cases 20 per 100 000	850 000 new cases 11 per 100 000	170 000 new cases 2 per 100 000
	Number of new hepatitis C infections per year	1.575 million new cases 20 per 100 000	1 million new cases 13 per 100 000	350 000 new cases 5 per 100 000
	Number of new hepatitis C infections per year among people who inject drugs per year	8 per 100	3 per 100	2 per 100
	Number of people dying from hepatitis B per year	820 000 deaths 10 per 100 000	530 000 deaths 7 per 100 000	310 000 deaths 4 per 100 000
	Number of people dying from hepatitis C per year	290 000 deaths 5 per 100 000	240 000 deaths 3 per 100 000	140 000 deaths 2 per 100 000
	Coverage	Hepatitis B – percentage of people living with hepatitis B diagnosed / and treated	30%/30%	60%/50%
Hepatitis C – percentage of people living with hepatitis C diagnosed / and cured		30%/30%	60%/50%	90%/80%

^a Latest data for end 2020. Some targets use data from 2019 because of COVID-19 related service disruptions in the data reported for 2020. COVID-19 is not currently expected to affect the targets for 2025. All data will be disaggregated by age, sex and when relevant the focus populations specific to the disease.

^b Please note that the targets in this table are global targets and should be adapted to set targets for countries in relation to the national context. For example, in some countries a target for hepatitis B surface antigen prevalence among children younger than five years may be less than 0.1% or 0.2%, although the overall global target should be 0.1%.

Coverage	Percentage of newborns who have benefitted from a timely birth dose of hepatitis vaccine and from other interventions to prevent the vertical (mother-to-child) transmission of hepatitis B virus ^c	50%	70%	90%
	Hepatitis B vaccine coverage among children (third dose)	90%	90%	90%
	Number of needles and syringes distributed per person who injects drugs ^d	200	200	300
	Blood safety – proportion of blood units screened for bloodborne diseases	95%	100%	100%
	Safe injections – proportion of safe health-care injections	95%	100%	100%
Milestones	Planning – number of countries with costed hepatitis elimination plans	TBD	30	50
	Surveillance – number of countries reporting burden and cascade annually	130	150	170
	Hepatitis C virus drug access – percentage average reduction in prices (to equivalent generic prices by 2025)	20%	50%	60%
	Hepatitis B virus drug access – percentage average reduction in average prices (alignment with HIV drug prices by 2025)	20%	50%	60%
	Elimination of vertical (mother-to-child) transmission – number of countries validated for the elimination of vertical transmission of either HIV, hepatitis B, or syphilis	15	50	100
	Elimination – number of countries validated for elimination of hepatitis C and/or hepatitis B	0	5	20
	Integration – proportion of people living with HIV tested for/and cured from hepatitis C	To be determined	60%/50%	90%/80%

^c In addition, the proportion of infants younger than 12 months of age who received the third dose of hepatitis B vaccine should also be measured as well as other indicators for preventing vertical transmission such as maternal testing and prophylaxis.

^d As part of a comprehensive harm reduction strategy and in line with national priorities.



Taking Action for Viral Hepatitis elimination

What are the inputs and outcomes? *Results chain*



INPUTS

- Political awareness, commitment & action**
- Community awareness and demand**
- Government engagement & leadership**
- Adequate funding (11.2 billion – 2021-30)**
- National Health care infrastructure (including clinical & lab, HCW, Data systems)**
- Affordable diagnostic products and treatment commodities (RDT, lab reagents, DAAs, TDF etc)**
- Partnerships- GF, GAVI, CHAI, others**
- Research & Innovation technologies (POC VL, person-centered monitoring)**

OUTPUTS AND OUTCOMES

Global public health goods for HIV, viral hepatitis and STIs are available

National policies and plans are evidence-based, up-to-date and funded

Evidence-based HIV, viral hepatitis and STI services are delivered with quality along the continuum of prevention, testing, treatment and care

Delivery of services is people-centred and tailored to diverse populations and settings, reducing inequalities

Health systems are jointly strengthened in relation to primary health care, data, governance, financing, workforce, commodities and service delivery

Communities are engaged and empowered to bring services closer to people and promote accountability

IMPACT

By 2030, End AIDS and the epidemics of viral hepatitis and sexually transmitted infections.

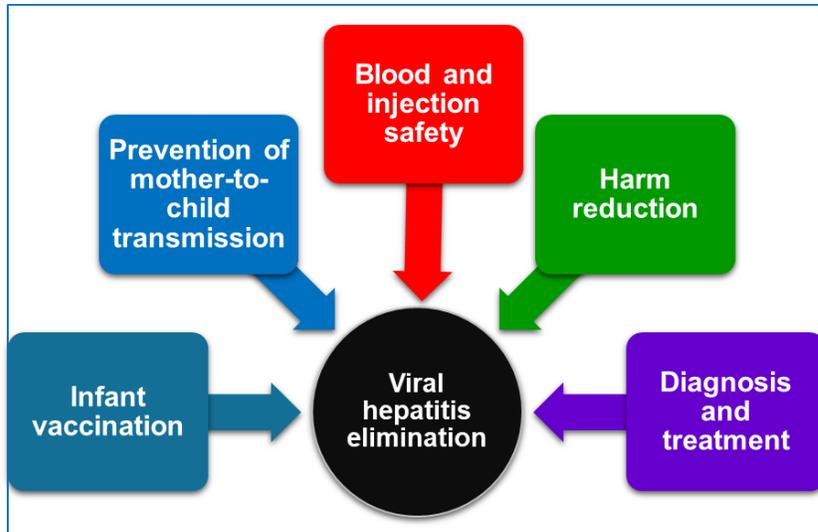
Advancing universal health coverage and health security



The VISION: Reaching elimination of viral hepatitis B & C by 2030 by implementing the 5 Strategic Directions of the HIV, VH, STI GHSS (2022-2030)



Actions to deliver elimination across the cascade



Key shifts required to end the epidemic of viral hepatitis by 2030

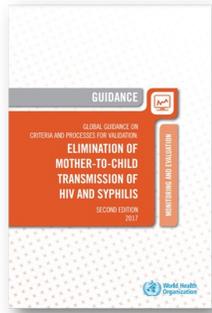


- **Greater public awareness** of the importance of viral hepatitis B and C prevention, testing and treatment
- **Strengthened community and civil society engagement**
- **Scale-up of universal access to hepatitis B birth dose vaccine** and improved services for prevention of vertical transmission
- **Continuous investment in primary prevention**
- **Greatly increased access to hepatitis B and C virus testing and treatment**
- **Simplified and decentralized service as well as integrated service delivery**
- **Development of curative drug regimens for hepatitis B virus**
- **Increased visibility and financial resources allocated**

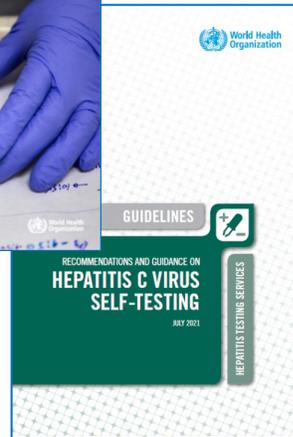
SD 1: Deliver high-quality, evidence-based, people-centred services

- Guidelines to improve the prevention, testing, treatment, and service delivery cascade for HBV, HCV, HDV
- **THE VISION – Consolidation of all guidelines & access on Knowledge management platform / Apps**

Prevention



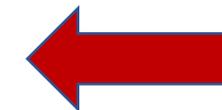
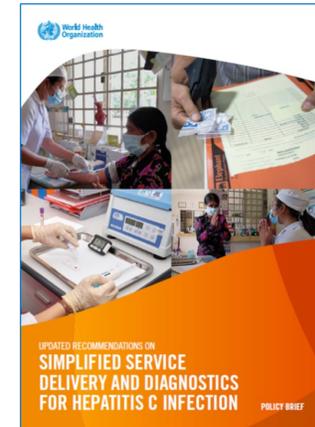
Testing/Diagnostics



Treatment

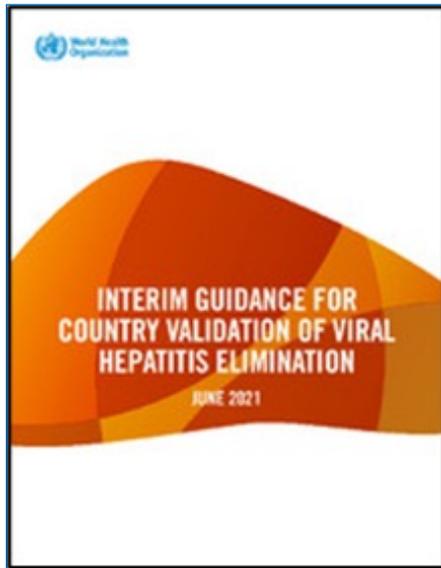


Service Delivery

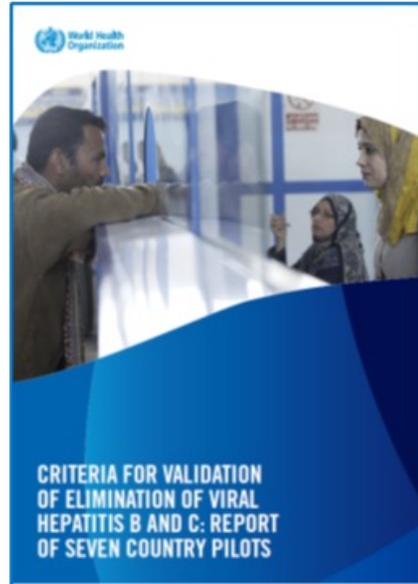


SD 2: Optimize systems, sectors and partnerships for impact

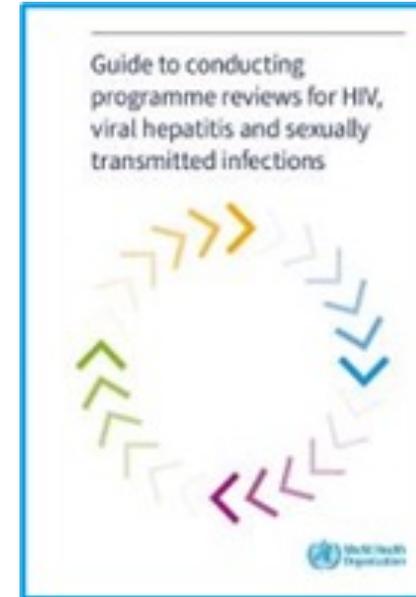
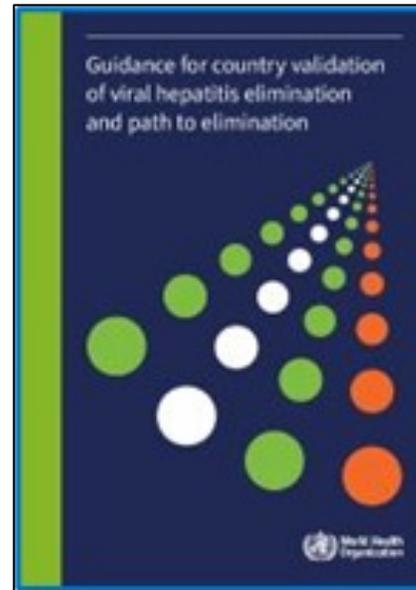
- Elimination guidance including PTE for Hep B & C
- Addressing models of integration with PHC/UHC – Hepatitis programmes in all country NSPs



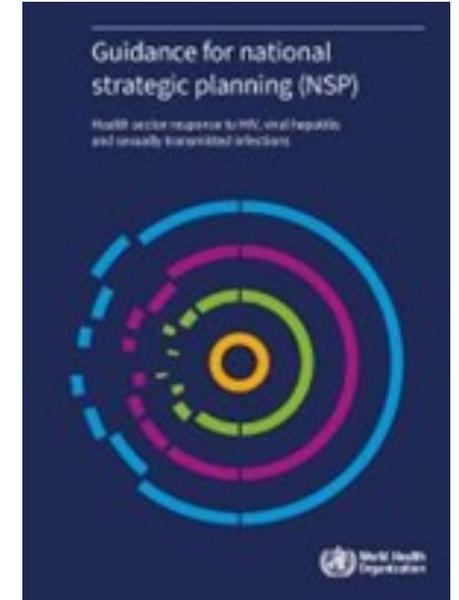
2021



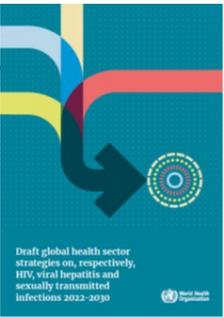
2022



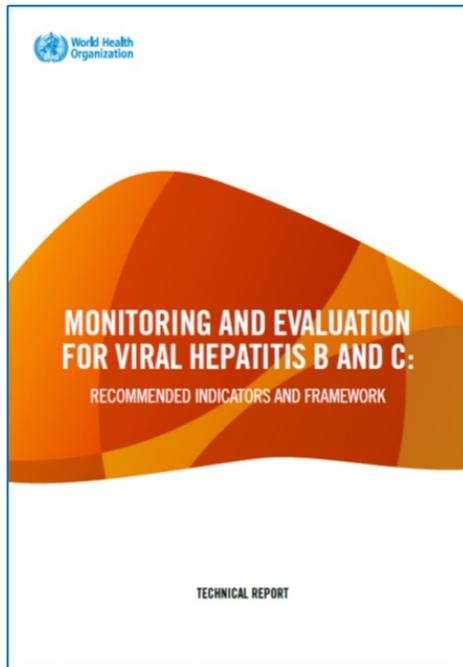
2023



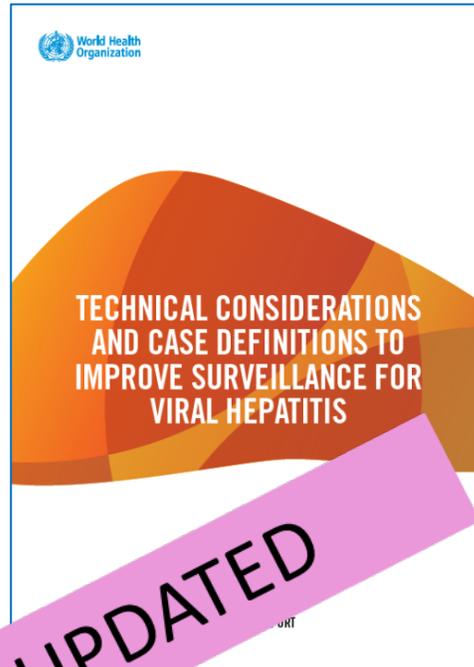
SD 3: Generate and use data to drive decisions for action



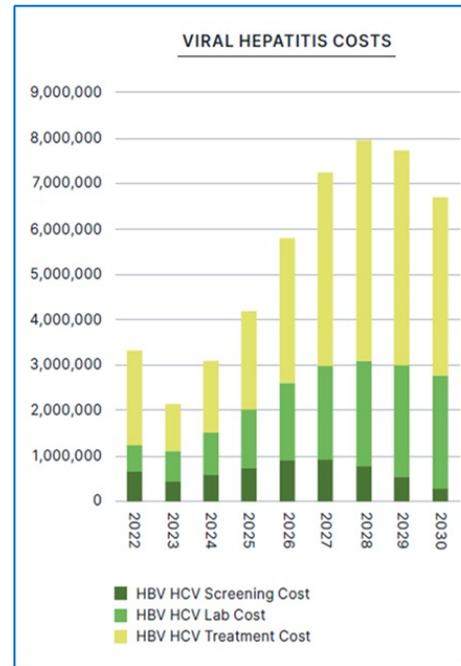
Updated SI guidelines



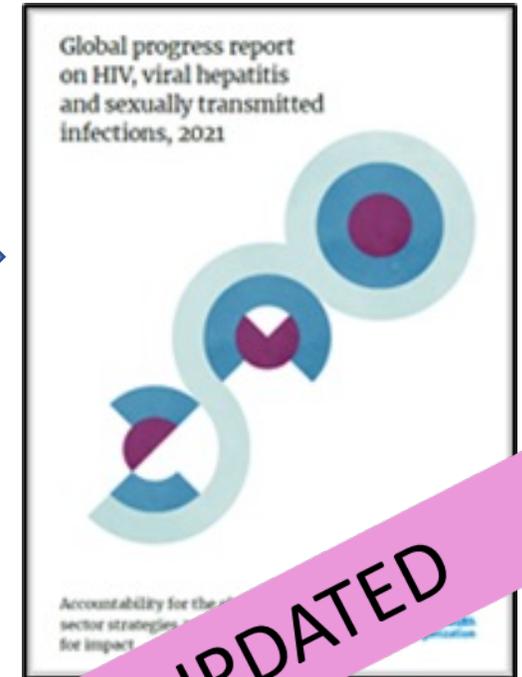
Person-centered data



Financing tools for response, Costed NSP



Updated Report for end 2023; WHA 2024

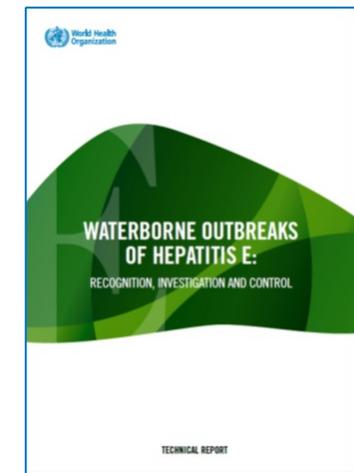
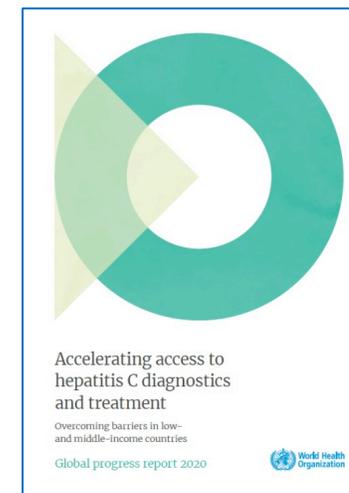
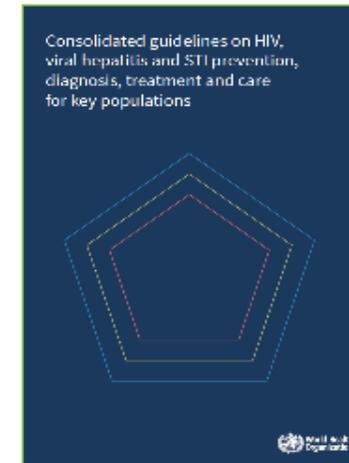


BEING UPDATED

BEING UPDATED

SD 4: Engage empowered communities and civil society

- Work with Communities affected by Hepatitis to disseminate and use the WHO Guidelines and guidance
- Support Key Population guidelines Implementation and use
- **Focus on increasing access**
 - Updated report on HCV/HBV access in 2023
 - Vaccine Hep E PQ advocacy



SD 5: Foster innovations for impact

- **CADO/PADO for Hepatitis B/C**
 - Scoping for LA-DAAAs
 - Watching brief on HEP B Cure
 - Paediatric regimens
 - Delta diagnostics/treatment
- **Harm Reduction innovations**
 - LA- Buprenorphine for OAT
 - Single use syringes
- **Service Delivery Innovations**

Indicators for the assessment of progress on the path to elimination of MTCT of hepatitis B in countries with an HBsAg prevalence >1% among ≤5 year olds and/or with general population prevalence exceeding 5%^a

	Impact targets	Programme targets
GOLD TIER	• Not necessary	<ul style="list-style-type: none"> • ≥90% coverage of hepatitis B 3rd dose infant vaccination • ≥90% coverage of universal timely hepatitis B birth dose • Antenatal hepatitis B surface antigen (HBsAg) testing coverage >30%
SILVER TIER	• Not necessary	<ul style="list-style-type: none"> • ≥90% coverage of hepatitis B 3rd dose infant vaccination • ≥50% coverage of universal timely hepatitis B birth dose • Antenatal HBsAg testing available in public sector
BRONZE TIER	• Not necessary	<ul style="list-style-type: none"> • ≥90% coverage of hepatitis B 3rd dose infant vaccination • Implementation of universal timely hepatitis B birth-dose policy

^a Programme targets should be achieved for 2 years.

Requirement for high coverage at the district level: e.g. ≥80% coverage in all districts for HepB3 in all tiers and ≥80% coverage in all districts for HepB-BD in gold tier and ≥50% for timely targeted HepB-BD in all districts for the silver tier.

Viral Hepatitis



New viral hepatitis diagnostics technologies and testing approaches. Continue to improve diagnostics technologies and testing approaches for simplified, timely and accurate hepatitis B and hepatitis C virus diagnosis and strengthened patient monitoring.



Optimized antivirals for hepatitis B and C virus. Support research on optimal doses and formulations of antivirals for hepatitis B and C virus.



New viral hepatitis vaccines. Promote the hepatitis C and hepatitis E virus vaccine agenda by promoting investments and visibility in efforts to secure a viable hepatitis C vaccine, including through strengthened collaboration with research and development-based partnerships, the private sector and communities.



Hepatitis B virus cure. Promote investments and visibility in efforts to secure a viable hepatitis B virus cure through strengthened collaboration with research- and development-based partnerships, the private sector and communities.

Partnerships for innovation. Optimize the potential for innovation through market analyses and strengthening research- and development-based partnerships, including strengthened engagement with the private sector.



What will it take to accelerate access

Significant scale-up of public health sector hepatitis programmes

1. Stepping-up of **political commitment** and government leadership,
2. National **planning and coordination**, development of evidence based national policy (NSP) and guidelines consistent with a **public health approach**
3. **Funding allocation** from national budget, donor and catalytic funding, developing an investment case, reducing costs of commodities (including pooled procurement etc)
4. Simplified and **decentralized treatment** at the strengthened primary care level,
5. Strong evidence -based **prevention services** – including blood and injection safety as well as harm reduction
6. **Subsidized cost** of care to populations
7. Surveillance, strengthen data systems for M&E and cascade data
8. Capacity building and training of **non-specialist physicians**.
9. Raising public **awareness**

*Addressing **ALL** the inputs in the results chain*

Measuring progress: Path-to-Elimination (PTE) for Hepatitis elimination

Goal: A focus on reaching programmatic targets without the immediate requirement to demonstrate incidence and mortality impacts

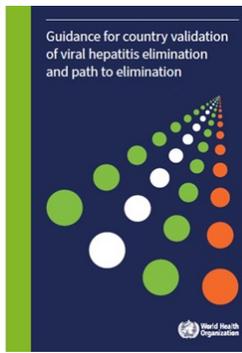


Table 1.1 Key interventions to address viral hepatitis with the GHSS on viral hepatitis and global targets (2022–2030)

Interventions	Bronze	Silver	Gold	Targets
				2030
1. Hepatitis B vaccination	• 90%	• 90%	• 90%	90%
2. HBV PMTCT ^a	• HBBD	• >50% & ANC	• 90% & ANC	90%
3. Blood safety	• 95%	• 100%	• 100%	100%
4. Injection safety	• 95%	• 100%	• 100%	100%
5. Harm reduction	• NSP	• NSP and OAT	• 150 NSP	300
6. Testing services	• 60% diagnosed • 50% treated	• 70% diagnosed • 60% treated	• 80% diagnosed • 70% treated	90%
7. Treatment			Sentinel surveillance	90%
				80% ^b
				80% ^c

HepB-BD: hepatitis B birth dose vaccine; HepB3: three doses of hepatitis B vaccine; PMTCT: prevention of mother-to-child transmission; PWID: person who injects drugs

Source: WHO, including commissioned work, United Nations, UNICEF

a Interventions to prevent mother-to-child transmission of HBV

b Of those eligible for treatment. Around 20–30% of persons living with HBV infections may develop progressive liver disease or HCC and are eligible for treatment with nucleoside analogue therapies;

c For HCV, all are eligible for treatment according to WHO guideline

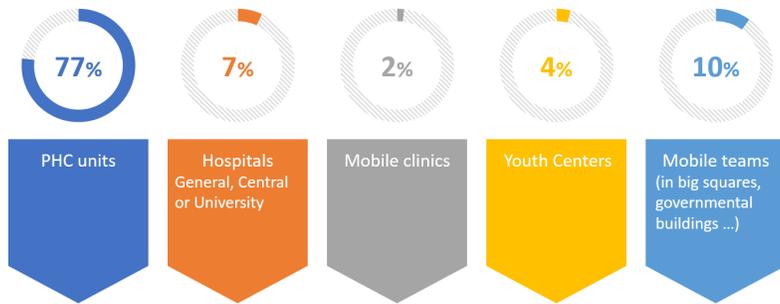
Rationale for PTE

- Evidence from implementation pilot and surveys and country experience
- Achievement of programmatic targets predict elimination
- **2025 targets for cascade are used as benchmark for the bronze.**
- Modification for progressive increase in harm reduction interventions

Egypt is the first country to receive the WHO “Gold tier” for hepatitis elimination

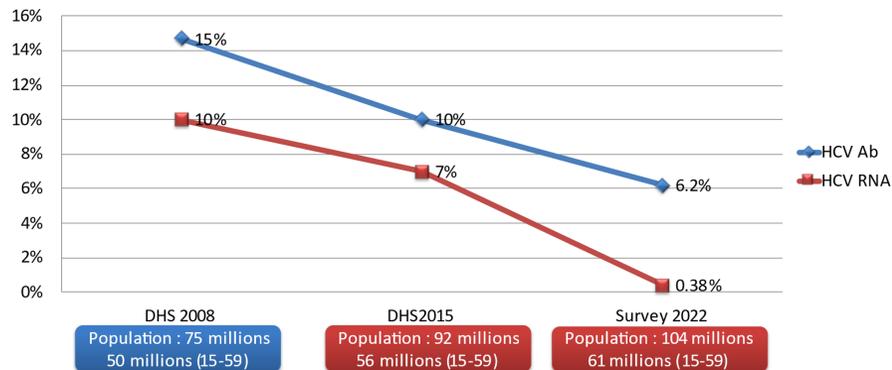
Decentralization and integration of testing in primary care was key

Screening sites



HCV prevalence (2008-2015-2022)

For Age group 15-59 years old



Congratulates highlights from the CHAI report

- WHO welcomes the third issue of the **HCV Market Intelligence Report** which shares market landscape of health products for hepatitis C.
- First time, this report also provides preliminary insights into the **market for harm reduction commodities for key populations.**
- **Note the evolving and expanding market for quality-assured, affordable HCV diagnostic products**
 - DAAs are more affordable than ever,
 - supported by a breakthrough pricing agreement of CHAI and The Hepatitis Fund with leading generic manufacturers.
- **Concerns for the future –**
 - lack of program scale-up in HCV and low demand visibility in LMICs are posing challenges to market sustainability.



Upcoming global report 2023 – Action for Access

- WHO is finalizing the next edition of the **Global Report on Viral Hepatitis**.
 - Report will cover both hepatitis B and C
 - Updated information on the **global epidemiology and service coverage worldwide**.
- Will complement the **CHAI HCV Market Intelligence Report** and unpack various dimensions of access to viral hepatitis products from a public health perspective.
- **WHO Report will focus on:**
 - Contributing factors to making products accessible to populations in need,
 - country-level adoption of WHO guidelines,
 - product regulation,
 - out-of-pocket expenditures, &
 - availability of products at primary healthcare level.
- Make recommendations for decision-makers to make effective use of existing opportunities, such as the **CHAI-Hepatitis Fund global pricing agreements, to expand their viral hepatitis programmes and make these products accessible at decentralized levels.**



WHO Report Objectives

Building on **2016, 2018 and 2020 reports**, the report will cover the following:

- **Global progress towards 2025 and 2030 targets** for viral hepatitis (GHSS 2022-2030 indicators on disease burden, service coverage, policy, and demand forecasts to 2030)
- **Global status of access to viral hepatitis products (diagnostics, treatment, vaccination)** (covering various dimensions of access, e.g. product registration, quality, intellectual property, pricing etc).
- **Practical considerations for WHO regions** to address access barriers (analysing regional specificities and featuring achievements in selected countries with WHO support)
- **Concrete policy options** or priority areas of action **by sector** (e.g. national authorities, industry, technical partners, funding partners, civil society, research inst., WHO)

WHO Report Information sources

1) WHO sources (HHS, MHP, RPQ departments), Regional Offices

- Global Hepatitis Reporting System (GHRS) - epi data, service coverage (cascade), policy milestones
- Other data on technical topics collected within WHO (e.g. patent status, prequalification status, product regulation, intellectual property)
- Regional and country analysis in collaboration with ROs and COs

2) Desk review

Published sources, e.g.:

- by WHO (e.g. normative guidelines, Global Progress Report 2021, GHSS 2022-2030, other WHO reports on access to health products)
- by key partners (e.g. MPP, CHAI, World Hepatitis Alliance, MSF Access Campaign, TAG, UNITAID, communiqués from pharmaceutical cos..)
- conference abstracts (e.g. World Hepatitis Summit 2022; EASL Viral Hepatitis Elimination Conference 2022)
- broader literature search as needed

Unpublished sources, e.g.:

- Internal WHO documents and presentations, e.g. from World Hepatitis Pre-summit 2022, WHO/UNAIDS global forecasting meeting Oct 2022

3) Consultations and key informant interviews

- Internal (WHO): e.g. HHS dept, MHP dept, RPQ dept, IVB dept, Regional Offices (and selected Country Offices as relevant)
- External (partners): e.g. MPP, CHAI, Global Hepatitis Alliance, MSF Access Campaign, UNITAID and others

Framework for analysing access to hepatitis B and C diagnostics and treatment products

Ref: WHO Road Map for Access to Medicines, Vaccines and Health Products 2019-2023



Fig. 2. Activities within the two strategic areas

Availability

Are services available in sufficient quantity?

Product availability (incl. innovations)
Normative guidelines and country plans
Financing landscape and mechanisms

Accessibility

Are services accessible to everyone?

Pricing and patents
Equity (reaching priority populations)
Health system inputs (procurement, HR, delivery)
Public awareness, access to information

Access
to viral hepatitis
diagnostics and treatment

Acceptability

Are services respectful, appropriate and sensitive to the needs of diverse priority population groups?

People-centred and differentiated service delivery
Community engagement
Non-discriminatory and rights-based approaches

Quality

Are services scientifically and medically appropriate and of good quality?

Product registration with national regulatory authorities
Quality assurance and prequalification

WHO Report Summary

- An urgent shift to a **public health approach** is necessary to make available health products accessible to all and advance towards the goal of elimination by 2030.
- The WHO report will analyze information on **38 WHO focus countries** for the viral hepatitis response, across the 6 WHO regions.
- **Among these countries, 10 countries** – China, India, Indonesia, Nigeria, Pakistan, Ethiopia, Bangladesh, Viet Nam, Philippines, and the Russian Federation - **comprise 67% of the global burden.**
- A special focus on these countries; along with special efforts in the African region where the prevalence of hepatitis B virus is the highest; will be essential to achieve global goals.
- WHO counts on the **collaboration of all partners and stakeholders to work with countries to make viral hepatitis health products accessible to all**, especially the most affected populations.
- Scheduled for publication at the **Global Hepatitis Summit April 2024**

Looking forward to 2024 - Accelerating access



Regional Office for Africa



Regional Office for the Americas



Regional Office for South-East Asia



Regional Office for Europe



Regional Office for the Eastern Mediterranean



Regional Office for the Western Pacific

- Implementing **Consolidated strategic information** for viral hepatitis
 - Data for improved action
- Accelerating **country actions & support for impact**: including Pakistan, India, Nigeria, South Africa, Vietnam, Egypt, Rwanda, Georgia, Ukraine
- **Models of integration** with PHC/UHC
- **Triple elimination** as an opportunity
- Resource mobilization



Thank You!

Acknowledgements
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Programme**

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Diane Faini
Daniel Low-Beer



HCV Diagnostics Highlights

Robia Islam, Senior Associate, Global Diagnostics Team, Hepatitis, CHAI

Overview of WHO-recommended HCV Diagnostic Tests

HCV Antibody Testing

WHO recommends use of a screening test to detect HCV antibodies as the first step. Screening tests may be done as a rapid diagnostic test (RDT) or laboratory-based immunoassay

UPDATED RECOMMENDATIONS

HCV self-testing

In 2021, WHO recommended HCV self-testing as an additional approach to HCV testing services

HCV Viral Load (VL)

All individuals who are HCV antibody positive should receive supplementary HCV VL testing to determine chronic infection. This can be done through a lab-based HCV RNA (qualitative or quantitative) or HCV core antigen (cAg)

Reflex testing

In 2022, WHO recommended use of reflex testing (immediate HCV RNA if HCV Ab positive) as an additional strategy to improve linkage to care

Treatment Assessment

WHO recommends assessments prior to treatment initiation including assessment of liver fibrosis using non-invasive testing e.g. APRI, FIB-4 to determine cirrhosis

Point-of-care (POC) HCV VL

In 2022, WHO recommended HCV POC VL can be offered as alternative for confirmatory testing or for test of cure

Monitoring

WHO recommends assessments of cure e.g. sustained virological responses at 12 weeks after the end of treatment. This can be done through HCV VL

More suppliers and products have recently been WHO prequalified for HCV antibody screening tests, signaling an expanding market



WHO PREQUALIFIED HCV ANTIBODY SCREENING TESTS

HCV ANTIBODY RDTs			
Product Name	Manufacturer	Sample Type	Time to Result
Bioline HCV	Abbott	plasma, serum, whole blood	5-20 minutes
STANDARD Q HCV Ab Test	SD Biosensor, Inc.	plasma, serum, whole blood	10 minutes
Rapid Anti-HCV Test	InTec PRODUCTS, INC	plasma, serum, whole blood	15 - 20 minutes
OraQuick HCV Rapid Antibody Test Kit	OraSure Technologies, Inc.	plasma, serum, whole blood, oral fluid	20 minutes
First Response HCV Card Test	Premier Medical Corporation	plasma, serum, whole blood	15 - 20 minutes
Hepatitis C Virus Rapid Test Device	ABON Biopharm	plasma, serum, whole blood	10 minutes

Recently WHO PQ'd

HCV ANTIBODY LABORATORY-BASED IMMUNOASSAYS				
Product Name	Manufacturer	Sample Type	Time to Result	Instrumentation
Monolisa HCV Ag-Ab ULTRA V2	Bio-Rad	plasma, serum	NA	Microplate Reader (Spectrophotometer)
INNOTEST HCV Ab IV*	Fujirebio Europe NV	plasma, serum	180 minutes	Microplate Reader (Spectrophotometer)
INNO-LIA HCV Score*	Fujirebio Europe NV	plasma, serum	NA	Auto-LIA (Immunoassay Analyzer)

- ❖ All HCV antibody RDTs and laboratory-based immunoassays have retained WHO prequalification (PQ) status
- ❖ In addition, two HCV RDTs have recently achieved WHO PQ status
- ❖ Beyond WHO PQ, additional stringent regulatory authorities (SRA) approved products, are available for procurement through major donors such as the Global Fund (*see report for details*)

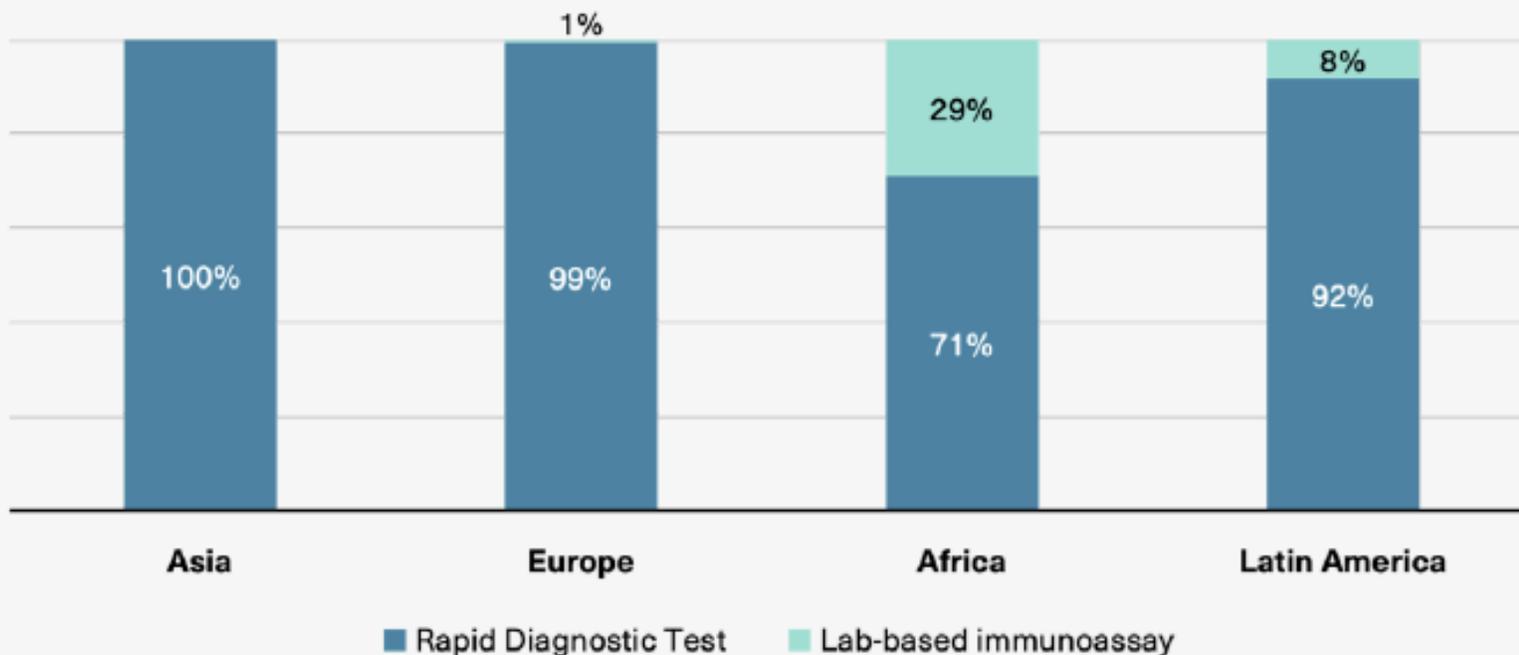
Source: WHO List of Prequalified In Vitro Diagnostic Products

*Both assays can be used to identify the detection of antibodies to human hepatitis C virus in serum or plasma, however the INNO-LIA HCV Score is intended for use as a supplementary test for those found to be reactive using anti-HCV screening

Procurement of HCV RDTs is significantly higher than lab-based immunoassays across countries, suggesting RDTs as preferred method of screening in low-resource settings



HCV screening assay type procured through Global Fund and publicly reported, by region (2016-2022)



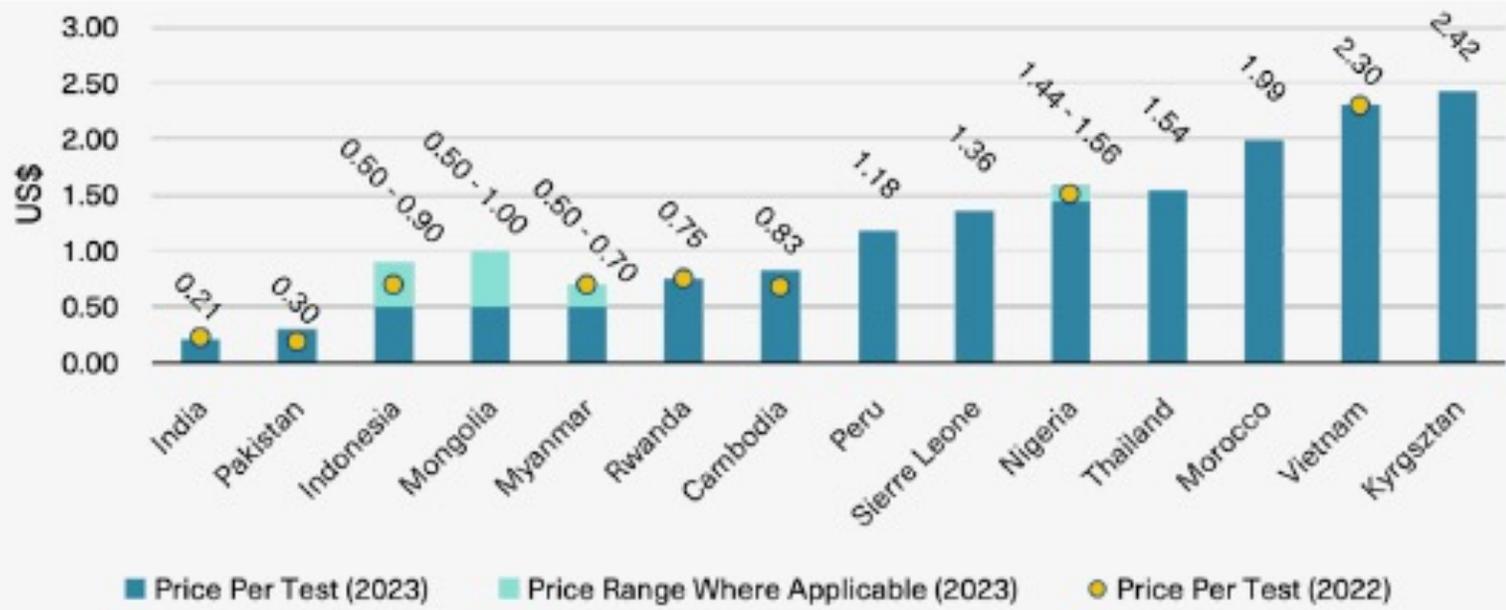
Source: GFATM [Price Reference Report](#) (non-exhaustive data from a sample of 43 countries which was available through publicly available procurement reports)

- ❖ Select procurement data from donors such as the Global Fund suggests preference for RDTs compared to laboratory-based immunoassays with **procurement of RDTs up to 24x higher than lab-based immunoassays**
- ❖ **Increased uptake in RDTs may be due to several programmatic and cost considerations** such as sample type, access to testing, logistical requirements, and time to result

In-country RDT prices often vary across countries ranging from as low as US\$0.21 to US\$2.42



Total price paid for HCV antibody RDTs in public programs within a sample of high-burden countries in 2023 (US\$)



Source: Pricing data reported by CHAI Country Teams and through the support of external partners such as FIND, MSF, and WHA
 Notes on Pricing: Prices in Vietnam are per the national health insurance policy. Previously reported prices for HCV RDTs ranged from US\$2 - 6 for public programs and included additional mark-ups by private service providers who also participate in the national health insurance scheme. In Myanmar, the range for prices reflects differences in the official exchange rate and the market exchange rates.

- ❖ RDTs are available through major donors such as GFATM, PAHO, and UNDP with global reference pricing around US\$ 0.80 - 1.10 ex-works
- ❖ However, the total price paid per RDT varies by country ranging from US\$0.21 on the low-end in India to as high as US\$2.42 in Kyrgyzstan
- ❖ Varying factors contribute to this including procurement mechanism used by governments and use of locally-produced products

An additional HCV VL test has attained WHO PQ, highlighting growing momentum around use of near POC VL technology to decentralize testing services



WHO PREQUALIFIED HCV VL TESTS

Product Name	Manufacturer	Platform	Sample Type	Time to Result	Price Per Test (US\$)*	Incoterm**
CENTRALIZED LABORATORY-BASED PLATFORMS						
Abbott RealTime HCV	Abbott	m2000 System (m200sp and m2000rt)	serum, plasma, dried blood spot (DBS)	96 results/8 hours	9.60 – 17.05	FCA
Alinity m HCV		Alinity m Instrument	serum, plasma	115 minutes	9.60 – 17.05	FCA
cobas HCV	Roche	cobas 4800	serum, plasma	384 results/8 hours	7.90	CPT
		cobas 5800	serum, plasma	144 results/8 hours		
		cobas 6800	serum, plasma	384 results/8 hours		
		cobas 8800	serum, plasma	1,056 results/8 hours		
NEAR POINT-OF-CARE PLATFORMS						
Xpert HCV VL Fingerstick	Cepheid	Cepheid GeneXpert Instruments	capillary and venous whole blood	75 minutes	14.90	EXW
Xpert HCV Viral Load		Cepheid GeneXpert Instruments	serum, plasma	105 minutes		

← Recently WHO PQ'd

- ❖ All HCV VL tests have retained WHO PQ status
- ❖ An additional test, intended for use on near POC platforms, has recently received WHO PQ, highlighting growing momentum around use of near POC VL technology
- ❖ Major molecular suppliers offer global access program (GAP) prices which range from US\$7.90 to US\$14.90, with varying terms and conditions to agreements
- ❖ Beyond WHO PQ, additional SRA-approved HCV VL tests are available for procurement through major donors (see report for details)

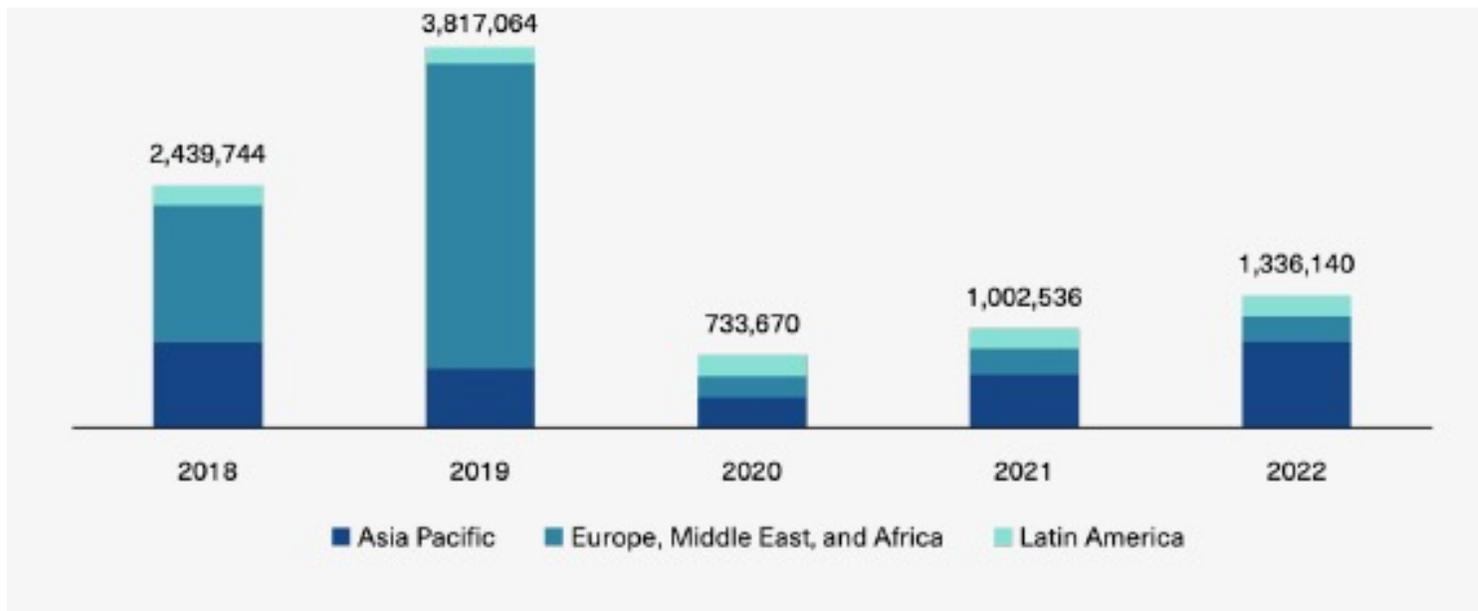
*African Society for Laboratory Medicine (ASLM) Molecular Supplier Pricing Database updated in May 2023 (see here); these prices reflect reagents and consumables only

**International commercial term defines who is responsible (seller or buyer) for paying of various activities throughout the trade process including loading charges, delivery, export duty, taxes, custom clearance, etc.

Data across major suppliers of HCV VL shows that sales peaked in 2019 at 3.8 Mn tests, largely driven by demand in Europe, Middle East, and Africa and GAP pricing agreement



Sale volumes of HCV VL assays from 2018-2022 across select countries & suppliers in GAP Pricing Agreement Countries (Non-Exhaustive)

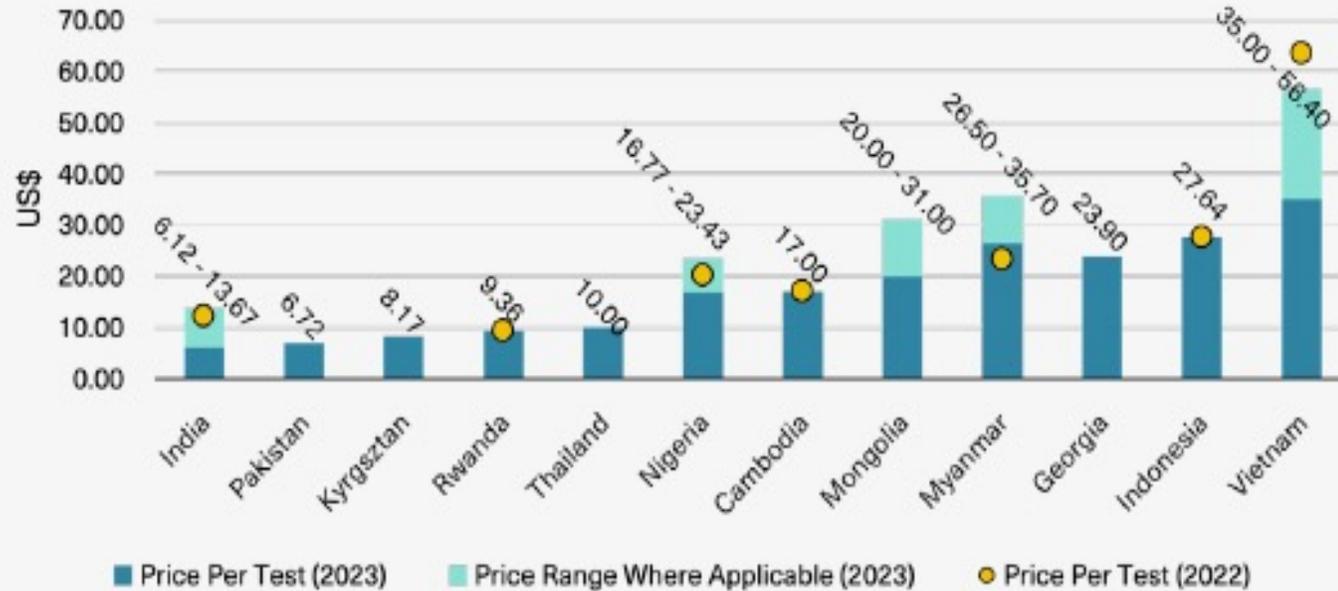


- ❖ Data collected across major VL suppliers demonstrates that sale volumes reached a peak of over three million in 2019
- ❖ Sale volumes likely dropped after 2019 due to:
 - ❖ Deprioritized investments into hepatitis programming because of COVID-19
 - ❖ High-burden elimination countries nearing targets (e.g. Egypt)
- ❖ Most sales were in Europe, Middle East and Africa Regions, attributing to 55% of sales
- ❖ From 2020 to 2022, Asia has steadily increased in volumes

In-country prices of HCV VL often vary across countries ranging from as low as US\$6.12 to US\$56.40



Total price paid for HCV VL in public programs within a sample of high-burden countries in 2023 (US\$)



- ❖ **GAP price agreements** offered by suppliers ensure that HCV VL tests are made available at affordable base prices
- ❖ **GAP agreements are negotiated on a country-by-country basis** and depend on conditions like instrument placements, test volumes, and service and maintenance
- ❖ Final prices paid for HCV VL vary by country and can range from **US\$6.12 on the low-end in India to US\$58.40 in Vietnam**
- ❖ Despite GAP agreements, **multiple cost components add to the final cost resulting in higher price paid per test**

New testing innovations can simplify testing, save time, and generate cost savings making testing more affordable, convenient, and accessible

HCV Self-Test

- ❖ Growing evidence suggests **HCV self-tests are acceptable** among key populations
- ❖ **Several products in the pipeline available for research use only**, with plans to enter market depending on regulatory approvals, pricing, and ongoing research and clinical trials

Product	Manufacturer
OraQuick HCV Rapid Antibody Self-Test	OraSure Technologies
First Response HCV Card Test (Self-Test)	PMC
Wondfo HCV Self-Test	Wondfo
HCV Self-Test	bioLytical

Dried Blood Spot (DBS) Specimen

- ❖ **DBS specimens simplify sample collection** and transportation, optimal for decentralized models of testing
- ❖ Products such as the Abbott RealTime HCV assay has WHO PQ including for use with whole blood spotted on DBS cards

HCV Core Antigen (cAg)

- ❖ **Alternative to HCV VL** confirmatory testing
- ❖ Evidence demonstrates that **HCV cAg as an alternative performs comparable well to traditional approaches**, however additional research needed in LMIC contexts

Product	Manufacturer	Sample Type	Time to Result	Regulatory Approval
Elecsys HCV Duo* (Qualitative)	Roche	plasma, serum	27 minutes	CE-IVD
ARCHITECT HCV Ag assay (Quantitative)	Abbott	plasma, serum	36 minutes	WHO PQ

*HCV Duo combines an HCV core antigen test with an anti-HCV test

Multiplex RDTs

- ❖ **Presents an opportunity to streamline and integrate screening** across multiple disease areas
- ❖ Preliminary research in Thailand demonstrates the **uptake and acceptability of 3-in-1 blood self-test for HIV, HBV, and HCV**



HCV Treatment Highlights

Navya Sharma, Senior Analyst, CHAI

While supplier landscape for DAAs remains robust with at least one generic PQ'd product, a few suppliers have exited the PQ market because of low product uptake

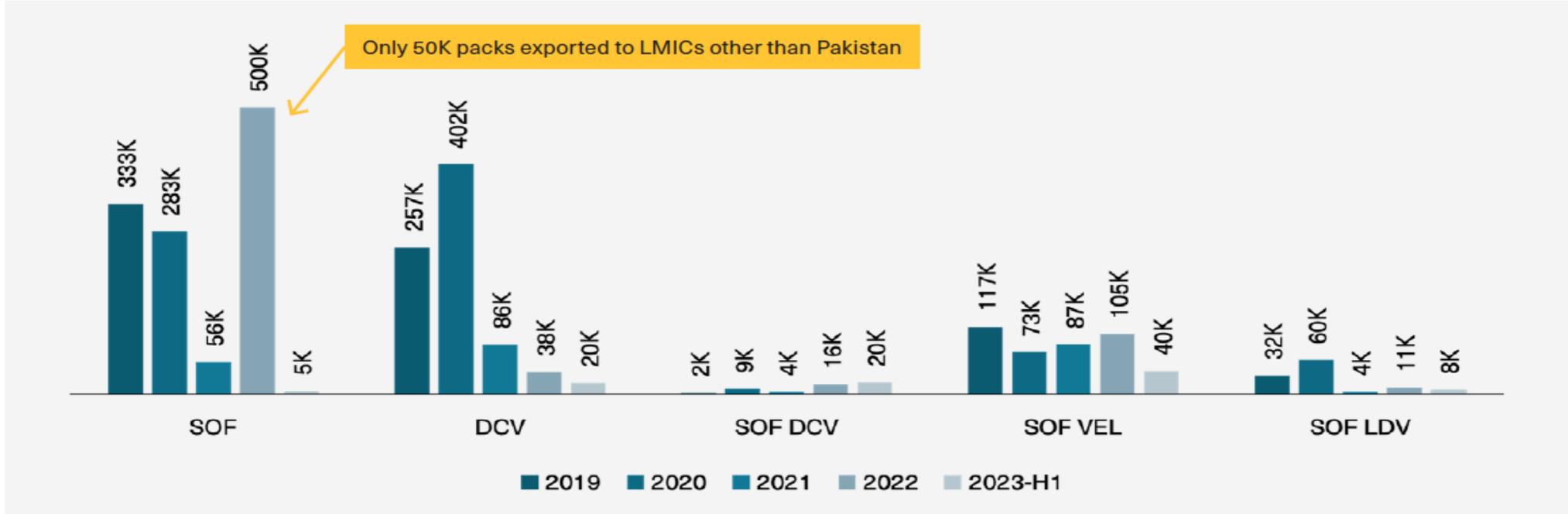
WHO PQ'd Suppliers of DAAs

DAA	WHO PQ	Suppliers that did not retain WHO PQ
SOF (400 mg)	Viartis, Hetero, European Egyptian Pharmaceutical Industry (Pharco), Strides Pharma	Cipla
DCV (30mg)	Hetero, Cipla, Laurus Lab	Viartis
DCV (60mg)	Hetero, Cipla, and Laurus Lab, Viartis	
SOF/DCV FDC (400 mg/60 mg)	Viartis	
SOF/VEL (400mg/100mg)	Viartis	
SOF/LDV (SOF/LDV) (400mg/90mg)	None	Viartis
SOF/VEL/VOX (400 mg /100 mg /100 mg)	SOF/VEL/VOX, which is recommended by WHO for retreatment of HCV, currently does not have a generic product in the market due to small and fragmented retreatment market.	
G/P (300 mg/120 mg)	In 2022, G/P was included in WHO's Expression of Interest for product evaluation to the WHO PQ, ²⁵ delineating a clear regulatory pathway for MPP licensees to file their generic formulations with WHO, if the product evaluation concludes in favor of G/P. Currently, there are no generics G/P products available in the market.	

- ❖ At least one generic supplier has received WHO PQ across key pan-genotypic treatment DAA regimens.
- ❖ Few suppliers have exited the WHO PQ market because of low product uptake.

Except for India and Pakistan, procurement volumes across most LMICs haven't recovered to the COVID-19 pre-pandemic level

Export of DAAs from India to LMICs (# of packs) from 2019 to H1-2023



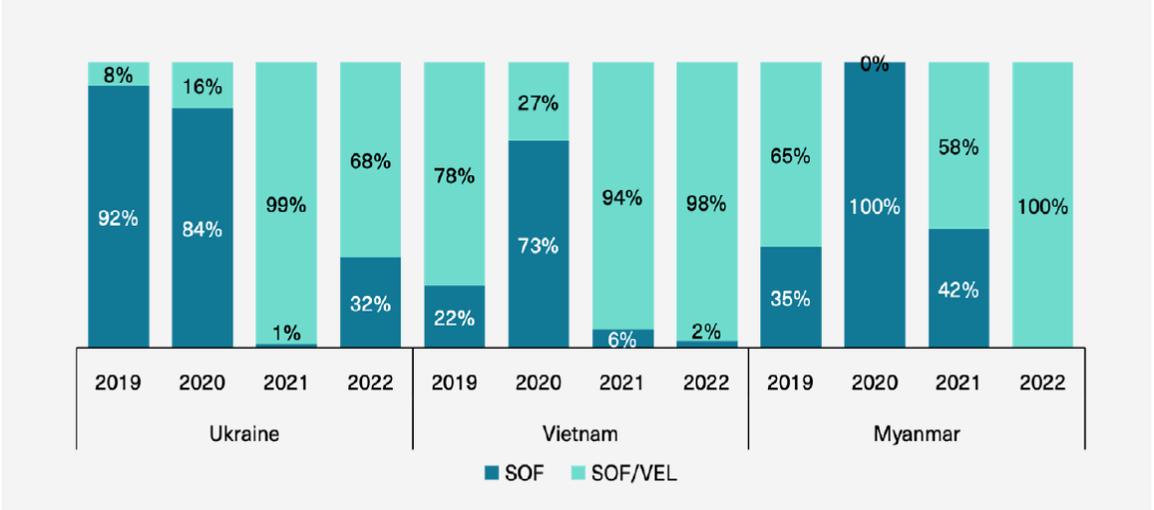
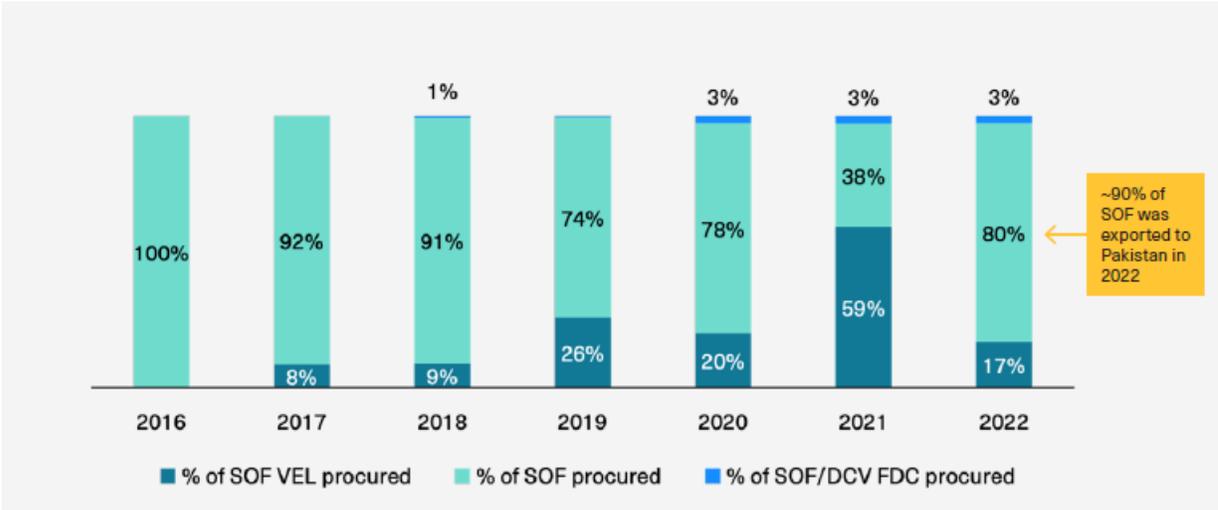
- ❖ Annual **DAA exports** from Indian generics to LMICs **increased** by 183% between 2021 and 2022.
- ❖ This **increase was primarily driven by Pakistan** which has procured nearly 450,000 SOF packs. Notably, Pakistan's SOF orders alone accounted for 67% of total exports in 2022.

SOF and DCV remain the preferred first-line treatment regimen, with a few countries opting to procure SOF/VEL



SOF and SOF/VEL exported from India to Ukraine, Vietnam and Myanmar between 2019-2022

SOF, SOF/VEL and SOF/DCV FDC exported from India since 2016 as a percentage of total export*

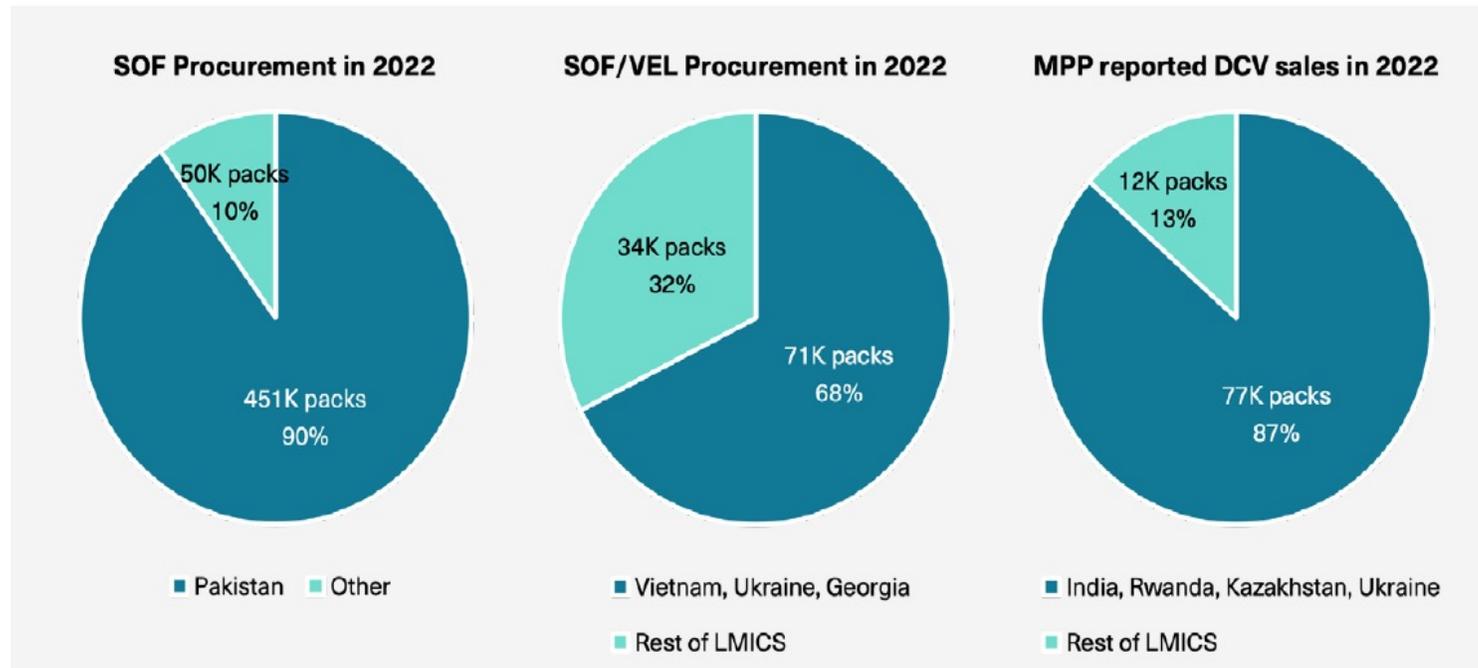


- ❖ In recent years, **some countries opted to import SOF/VEL** instead of individual drugs like SOF and DCV from Indian generics as the data shows.
- ❖ This change in preference for specific DAA combinations further influenced the shifting dynamics of India's DAA exports.

*Note: SOF volumes are used as a proxy for SOF and DCV regimen volumes. DCV volumes have not been included in calculation of total exports for this graph as SOF and DCV are drugs prescribed as a combination treatment.

DAA market exhibits a recurring trend of buyer concentration

Buyer concentration of DCV 60mg, SOF/VEL, and SOF (Singles) procurement in 2022



- ❖ DAA market exhibits a **recurring trend of buyer concentration** with a few countries accounting for most of the DAA procurement over the years.
- ❖ Sustainable demand must be generated to improve market health.

Pricing breakthrough reduces the cost of viral hepatitis treatment

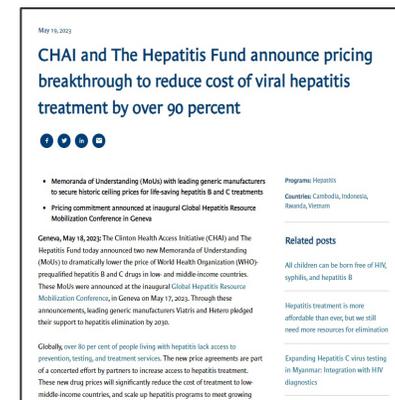
In May 2023, CHAI and The Hepatitis Fund signed a ceiling price agreement with two generic manufacturers of hepatitis drugs

- ❑ 12-weeks course of SOF and DCV to be offered at a ceiling price of **US\$60**
- ❑ TDF 300mg at or below **US\$28.8 per patient per year**
- ❑ All products offered would be either US-FDA approved or WHO pre-qualified

Who can access the agreement?

- Any organization or entity that is purchasing these medicines on behalf of public sector
- Patients in the territory as per the licensing agreement of generic manufacturers with innovators

Please visit [CHAI's Website](#) for more information on the pricing agreements and FAQs



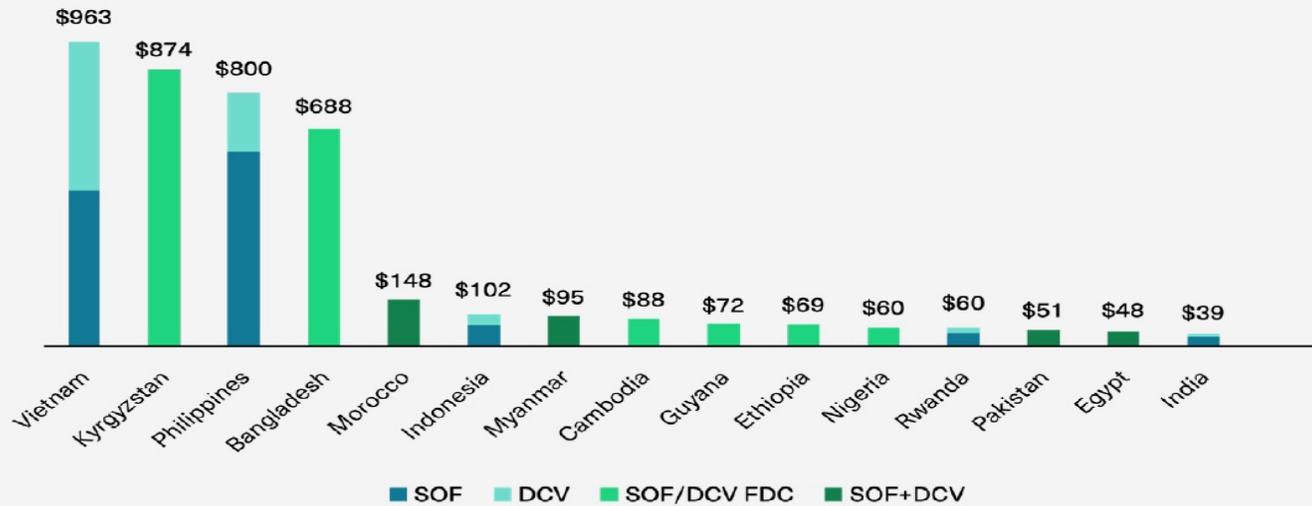
Global Reference Pricing	Org/Regimen	SOF/DCV FDC	SOF/DCV	SOF/VEL
	GFATM	US\$60	US\$63	US\$174
	PAHO	US\$72	US\$57	US\$4,050 ¹ US\$174 ²
	UNDP	US\$74.55	-	US\$202.50

Note:1. Innovator product price; 2. Generic product price

❖ Global Fund’s reference pricing decreased for treatment courses of SOF/DCV FDC and SOF and DCV singles combination.

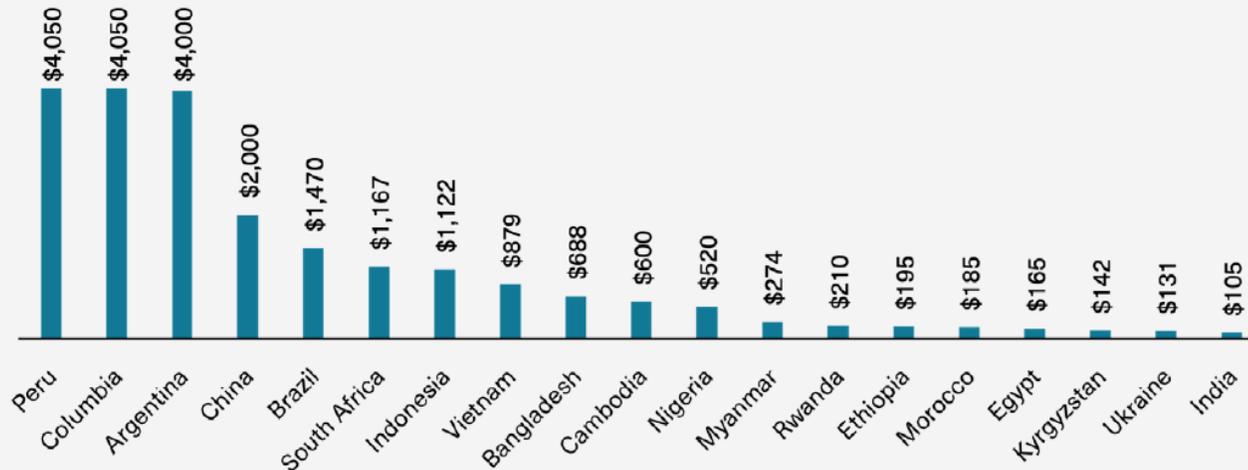
There is significant variability in DAA prices accessed across LMICs

In-Country Price for SOF/DCV



- ❖ DAA prices have fallen significantly due to the expansion of the competitive landscape of generic DAAs and the increase in demand.
- ❖ However, there is significant **variability** in prices accessed across LMICs **driven by fragmented demand, sub-optimal procurement practices, and geo-political instability** in some regions.

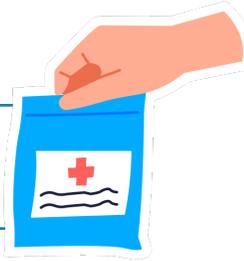
In-Country Price for SOF/VEL



WHO guidelines on HCV testing and treatment of adolescents presents an opportunity for immediate, rapid scale-up of HCV services



In September 2021, 200 mg of SOF was included on the WHO Model List of Essential Medicines for Children.



In June 2022, WHO released updated guidelines which expanded the DAA market by recommending pan-genotypic DAA regimens for adolescents and children.



In October 2022, SOF 200mg was included on the list of products eligible for WHO PQ



WHO Guideline SOF and DCV recommendation for adolescents presents an opportunity for immediate, rapid scale-up of HCV services as the available adult formulations are accessible and affordable across a majority of LMICs



Strategies for Sustainable and Affordable Access to HCV Diagnostics and Treatment in LMICs



Pricing breakthrough paves way for rapid scale-up



Efforts from global community needed to reach HCV elimination...

1

Commit to HCV Management in Public Healthcare Systems

2

Ensure Patient Savings and Access to Global Access Pricing for HCV Commodities

3

Improve Procurement Practices

4

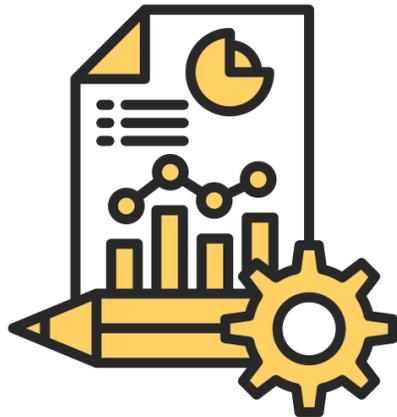
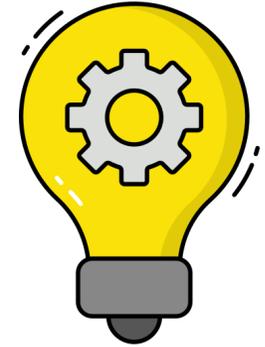
Optimize Existing Resources through Integration

5

Develop Market Projections

6

Establish Public-Private Partnerships





Harm Reduction Highlights

Navya Sharma, Senior Analyst, CHAI

Umesh Chawla, Associate Director, Hepatitis Program, CHAI

2023 HCV Market Report scope includes harm reduction commodities

Preliminary Insights into Harm Reduction



OAMT Commodities

OAMT- Methadone & Buprenorphine
(marker snapshot on next slide)



Overdose prevention commodities

Naloxone



Needles and Syringes used in Harm Reduction Programs

HCV Prevention and Harm Reduction Services Are Urgently Needed

- ❑ ~**15.2%** of people who inject drugs have HIV infections, **38.8%** have HCV infection, and **8.4%** have HBV infection
- ❑ Globally, **43%** of new HCV infections are attributed to injection drug use with regional variation



HARM REDUCTION AND HCV ELIMINATION:
There is a need for market transparency and increased resource commitment to harm reduction to effectively implement HCV prevention strategies

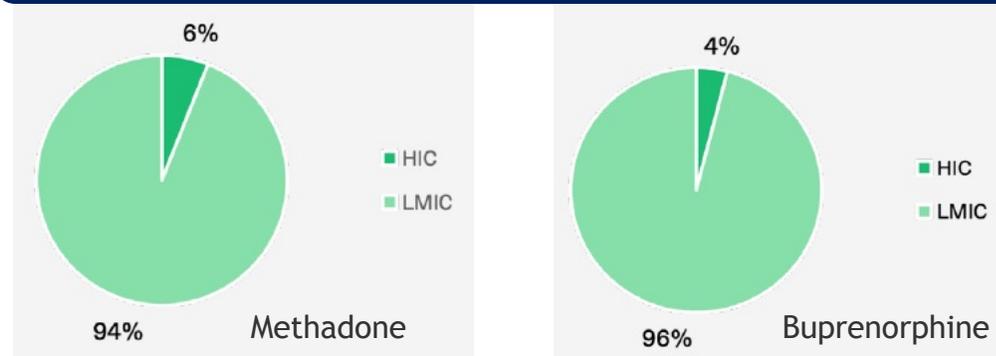
Manufacturing & consumption of OAMT commodities concentrated in high-income countries

Indicative Trends for OAMT Commodities

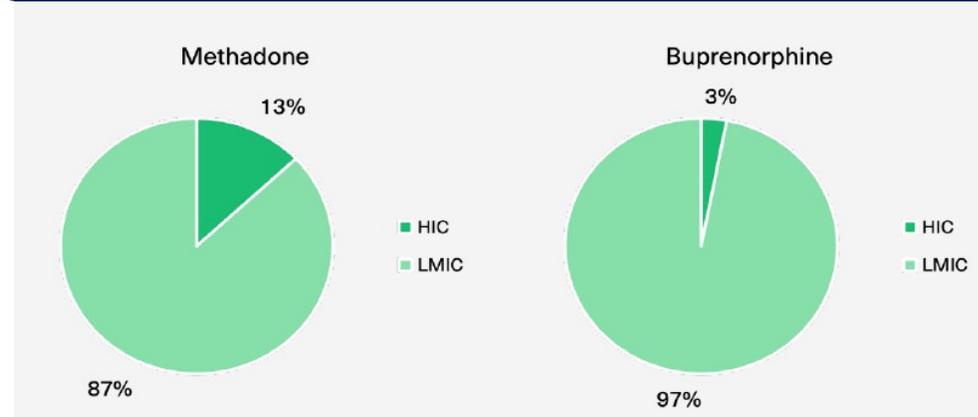
	<p>While methadone and buprenorphine do not have WHO PQ'd products in the market, SRA-approved products are available.</p>
	<p>Manufacturing and export concentrated in HICs; India is the only major manufacturer in LMICs.</p>
	<p>Consumption is disproportionately higher in HICs as opposed to LMICs; methadone consumption is two times larger than buprenorphine consumption in LMICs.</p>
	<p>The cost for a one-litre bottle of Methadone varies between approximately \$16-\$230 <i>~\$230 is average the single exit price for South Africa; Across other LMICs price varies between \$16-\$24. ^{2,3}</i></p> <p>The cost per 2mg tablet of Buprenorphine varies between approximately \$0.06-\$2.5³</p>

Note: 1. Please note that these prices and trends are highly indicative 2. Single exit price for RSA is a ceiling price in the country; 3. Prices were collected across a sample of countries.

Methadone and Buprenorphine manufactured in LMICs and HICs between 2015-2020



Methadone and Buprenorphine consumed in LMICs and HICs between 2015-2020



The scale of overdose reversal services remains low in LMICs

- ❖ Naloxone, the recommended commodity for overdose reversal is typically used in injectable formulations in LMICs.
- ❖ **Access to naloxone varies widely** and in many regions, access to naloxone is via prescription and only in medical settings, and in certain regions, naloxone availability is even more limited to specific medical settings, e.g., ambulances.
- ❖ An analysis of 199 countries, found that only about 10 LMICs have take-home naloxone available, and 78 percent of countries did not have a naloxone peer distribution program in operation.
- ❖ In 2022, Indian generics exported US\$2.63 million worth of Naloxone across 55 countries. However, only 4 percent of these exports were to LMICs that mostly procure injectable formulations of naloxone.
- ❖ Pricing of Naloxone varies across LMICs between US\$0.50 to US\$9.10; there is **no global benchmark pricing available** for the commodity.

Choice of needles & syringes used in harm reduction programs varies across countries - Current coverage: 17%; Global need: 3 Bn needles & syringes



- ❖ All individuals from key populations who inject drugs should have access to sterile injecting equipment through NSPs. (WHO)
- ❖ Product selection should be tailored to local population needs and preferences as **one type of syringe will not fit all needs.**
- ❖ WHO recommends that based on local acceptability and resource availability- NSPs also provide LDSS, along with information about their preventive advantage over conventional syringes
- ❖ **No WHO mechanism** exists for PQ of needles and syringes; appropriate guidance on the quality status and requirements for these commodities, and availability of the most appropriate product designs for use in NSP across countries.
- ❖ There is an unfulfilled demand gap in the market which suppliers can leverage as there is a need for over three billion needles and syringes distribution annually through these NSP sites to achieve high coverage.

Harm reduction strategies can contribute to the global goal of eliminating HCV as a public health threat





Country Perspective: Nigeria

Chukwuemeka Agwuocha, Program Manager, Hepatitis/COVID-19 Therapeutics, CHAI
Olayinka Adisa, Senior Analyst, Health Systems Strengthening/Access, CHAI



Market shaping work in Nasarawa



Role of market report and pricing agreement to achieve reduced pricing

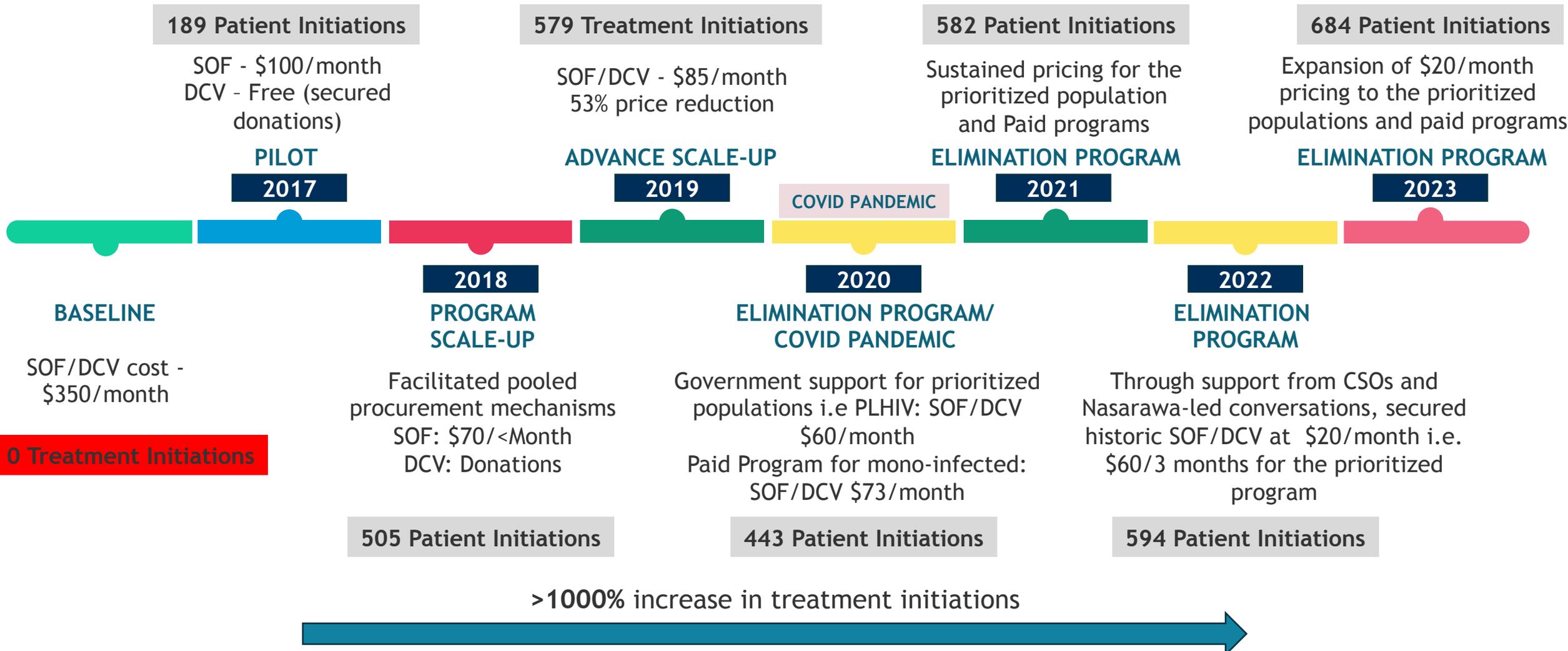


Future Opportunities

Since 2017, CHAI has worked with the government and other stakeholders leveraging the market intel to secure price reductions for HCV commodities



94% decline in cost from baseline



>1000% increase in treatment initiations



CHAI, in partnership with the Hepatitis Fund, secured price agreements that ensures access to viral hepatitis treatments for all



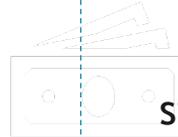
Domesticating the global TDF pricing in Nigeria demanded the following approaches:

1

Leverage Market intel to secure global pricing deals

2

Identify opportunities to domesticate pricing and build an investment case



3

Secure partner collaborations (CSOs), government, and other stakeholder commitment

4

Negotiate pricing deal with Pharma, confirm payment terms, facilitate LPO, ensure supplies and distribution to facilities

Leveraging the Market Report

1

Market Analysis

Determine existing in - country pricing

2

Supplier Assessment

Map in - country actors, i.e., Hetero & Viatris

3

Demand & Supply insights

Program planning

4

Competitive positioning

Increase market visibility

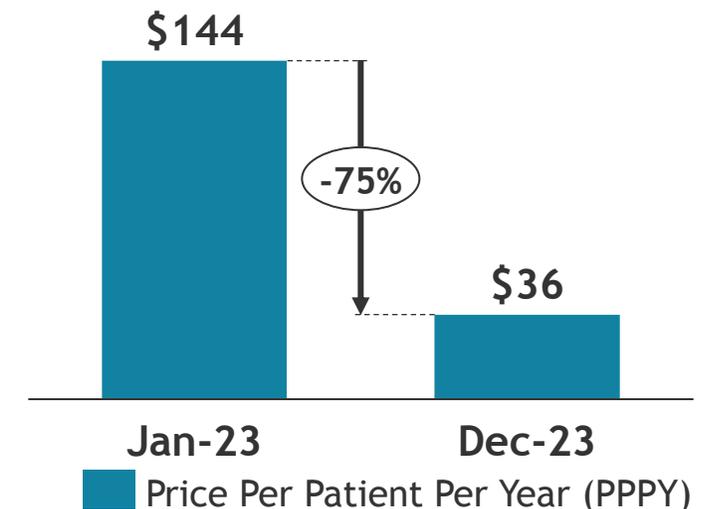
5

Identifying cost drivers

Determine supply chain and foreign exchange bottlenecks



HBV Treatment



Lessons learned will catalyze access to emerging diagnostics and treatment trends to achieve viral hepatitis elimination



01

Drive Triple Elimination interventions in ANC

- Integrated testing options to include HBV
- HBeAg single tests in resource limited settings
- Scale up TDF access pricing across the country

02

Expand Access to Pricing Deal - Resource Mobilization

- Secure donor funding i.e.; GC7 support, domestic resource mobilization and private sector investments (device placements, donations, commodity procurement, etc.) for HBV PMTCT programming in - country





Community Perspective

Annie Madden, Project Lead, International Network of People Who Use Drugs (INPUD)

The Importance of Market Intel on Harm Reduction Commodities



Dr Annie Madden, Project Lead



CUTTS HEP C - PROJECT

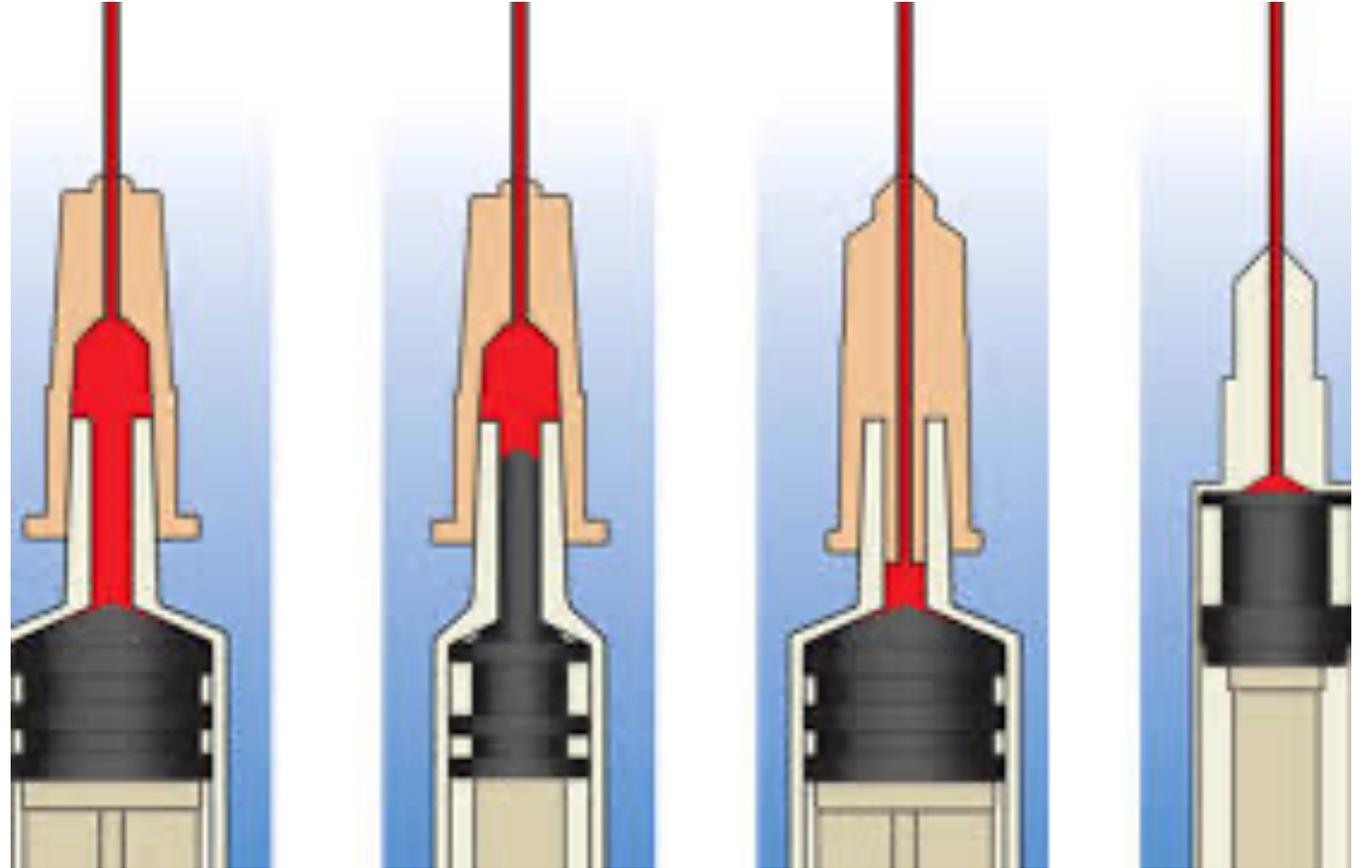
Simplifying hepatitis C pathways in LMICs

MdM Consortium...



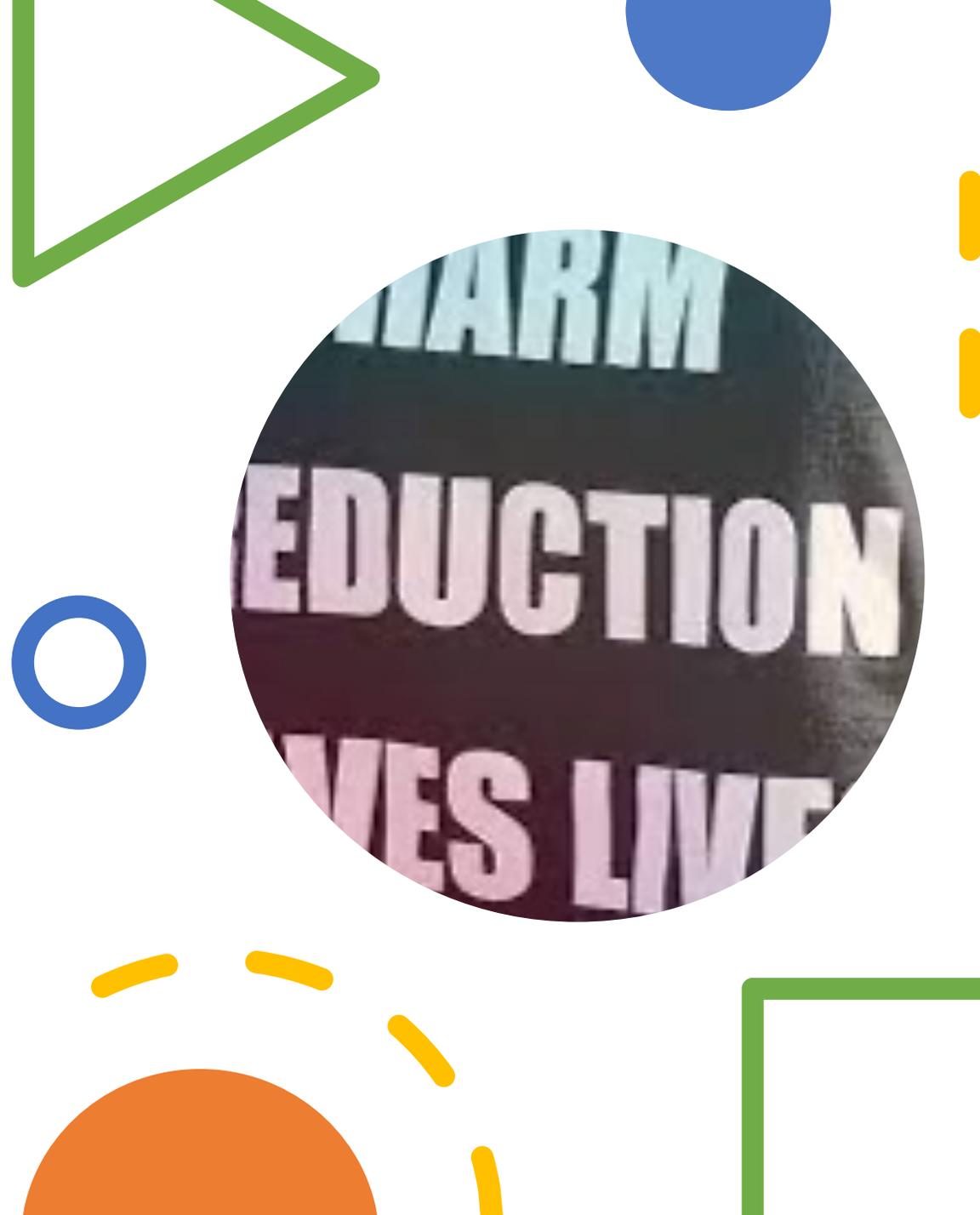
Low Dead-Space Syringes & Needles (LDSS/N)

- Reducing the 'dead-space' between the end of the plunger and in and around the needle hub to reduce the amount of blood that remains in the syringes after injection.
- Research in HIC has identified the potential for LDSS/N to reduce HCV transmissions if N&S are reused.
- Increase in funding for harm reduction and improvements in access in LMICs *but...*
- Still a long way to go both re: country procurements bids & donor procurement practices (GF).



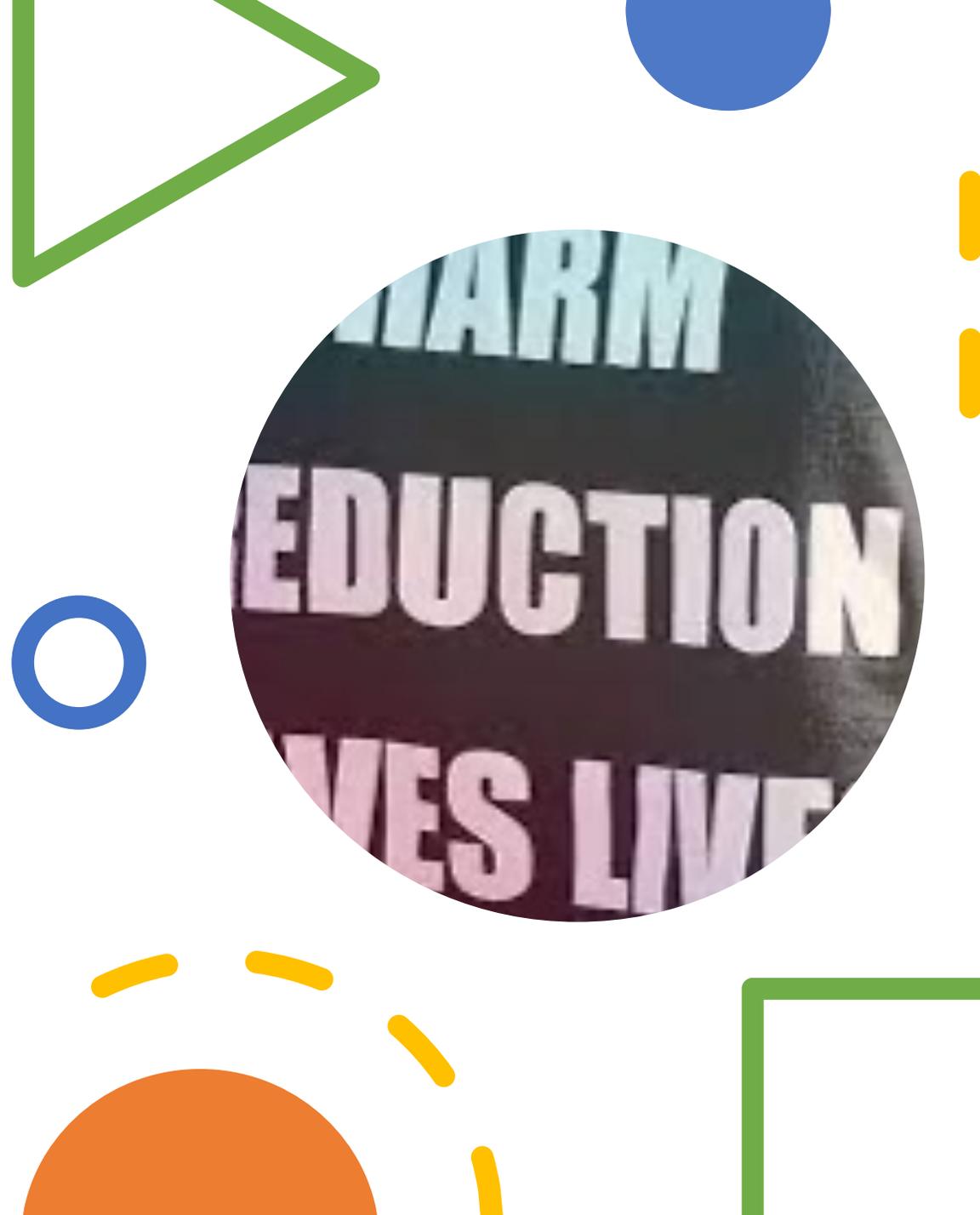
Importance of Market Intel for Harm Reduction Commodities

- This is why good market intel on harm commodities is so important!
- We know harm reduction works and saves lives, but only if:
 - Access and availability/coverage **AND...**
 - If we get the right harm reduction commodities to the people who need them!
- Currently HR commodities in LMIC are constrained by global procurement processes (GF).
- PWID often only have access to one option/limited options and there's insufficient access/coverage.
- Can result in PWID only having access to auto-destruct N&S and/or over-sized equipment – not 'fit for purpose' and increase HCV transmission risk:
 - More vein damage & scarring
 - More blood during injecting process (sites, hands, surfaces)
- The legal environment can also affect how PWID make use of available HR commodities/undermine HR practices.



Importance of Market Intel for Harm Reduction Commodities

- This is why it is so important for HCV to get HR commodities right! What is the best way to do that?
- Community engagement and consultation with PWID.
- Drugs and drug using practices differ from place to place.
- No 'one-size fits all' approach – despite that this is what is happening with global donor procurement practices BUT...
- Consulting & engaging means listening and then acting on the expert advice PWID give. Don't ask and then ignore!
- PWID know what they need and why – their daily lives.
- Sometimes people 'don't know what they don't know' e.g., is it a 'preference' or just what people are familiar with?
- Reach out to INPUD/regional PWUD networks – they can work with local PWID communities to show what's possible and identify local needs and tailored solutions.
- Achieving HCV elimination goals = working with PWID to understand and then meet their specific harm reduction needs.





Donor Perspective: Global Fund

Shaun McGovern, Advisor HIV Product Introduction, Global Fund



Q&A

Ritubhan Gautam, Manager, Global Markets Team, CHAI

Umesh Chawla, Associate Director, Hepatitis Program, CHAI

Panelists

- Oriel Fernandes, Senior Director, Hepatitis Program, CHAI
- Meg Doherty, Director, Global HIV, Hepatitis and STI Programmes, World Health Organization
- Robia Islam, Senior Associate, Global Diagnostics Team, Hepatitis, CHAI
- Navya Sharma, Senior Analyst, CHAI
- Chukwuemeka Agwuocha, Program Manager, Hepatitis/COVID-19 Therapeutics, CHAI
- Olayinka Adisa, Senior Analyst, Health Systems Strengthening/Access, CHAI
- Annie Madden, Project Lead, International Network of People Who Use Drugs (INPUD)
- Shaun McGovern, Advisor HIV Product Introduction, Global Fund
- Ritubhan Gautam, Manager, Global Markets Team, CHAI



Closing Remarks

Oriel Fernandes, Senior Director, Hepatitis Program, CHAI