Real-world progress on hepatitis C elimination and future implementation challenges: Implications for people who inject drugs

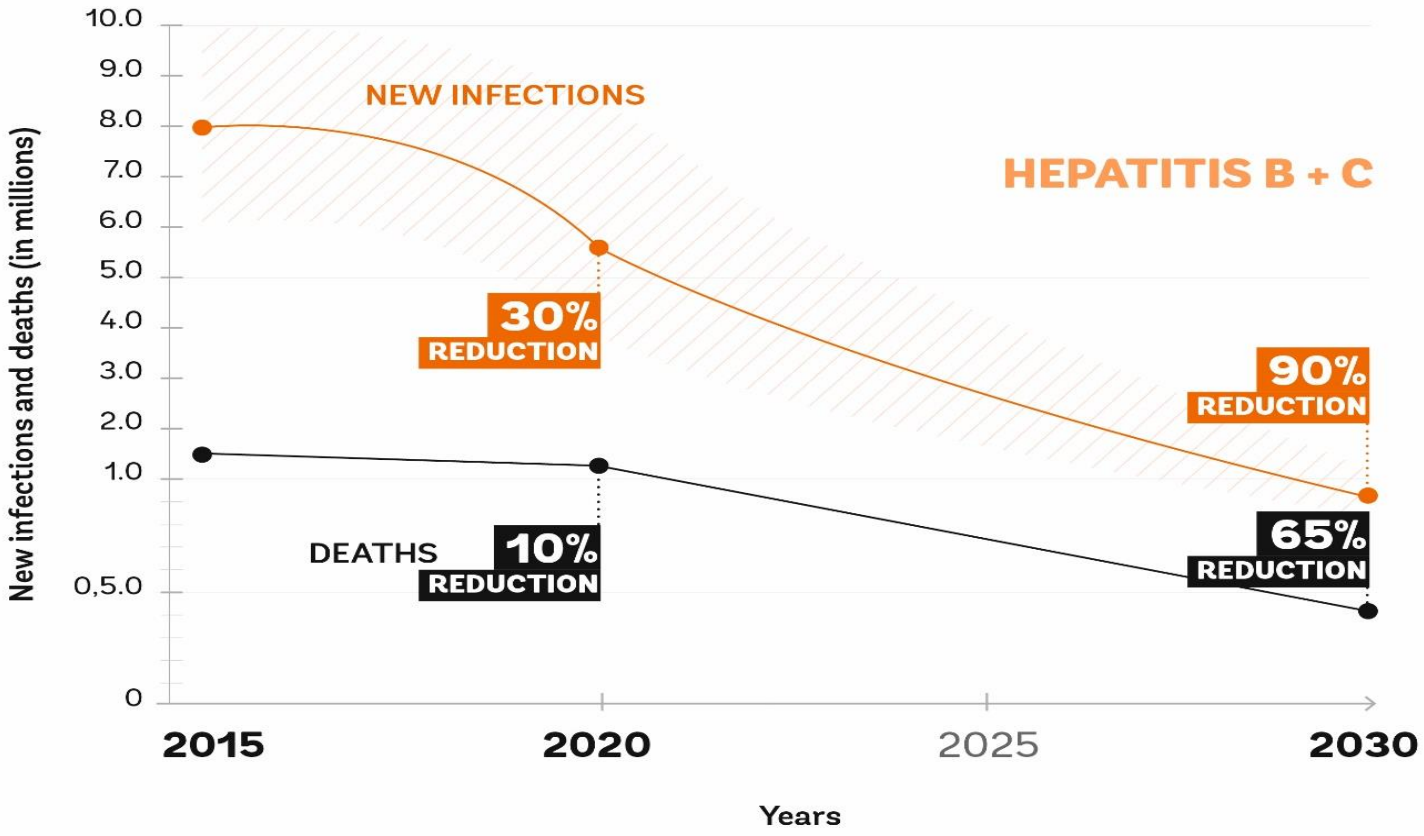
World Health Organization

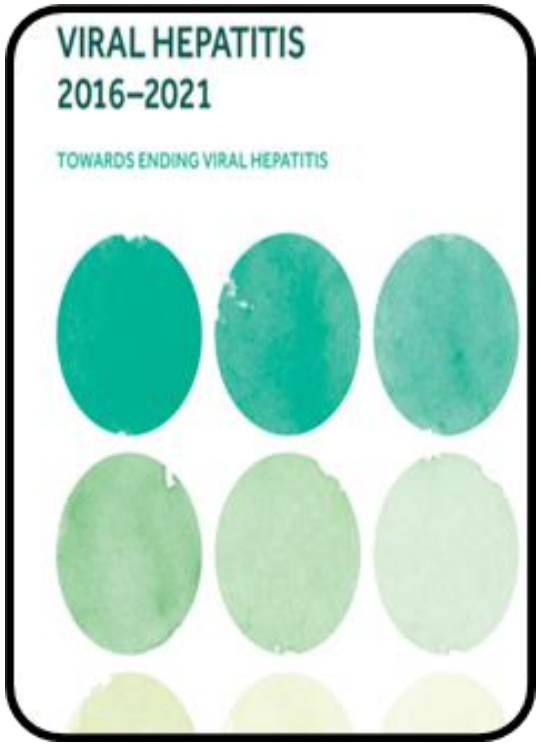
Dr Niklas Luhmann, WHO HQ

Virtual INHSU 2021 conference; Sydney October 2021

Global HCV elimination: What is the situation ?

WHO's aim is to **eliminate viral hepatitis** as a major public health threat **by 2030**





Global Health Sector Strategy, WHO, 2016

6-10 million infections (in 2015) to 900,000 infections (by 2030)

1.34 million deaths (in 2015) to under 500,000 deaths (by 2030)

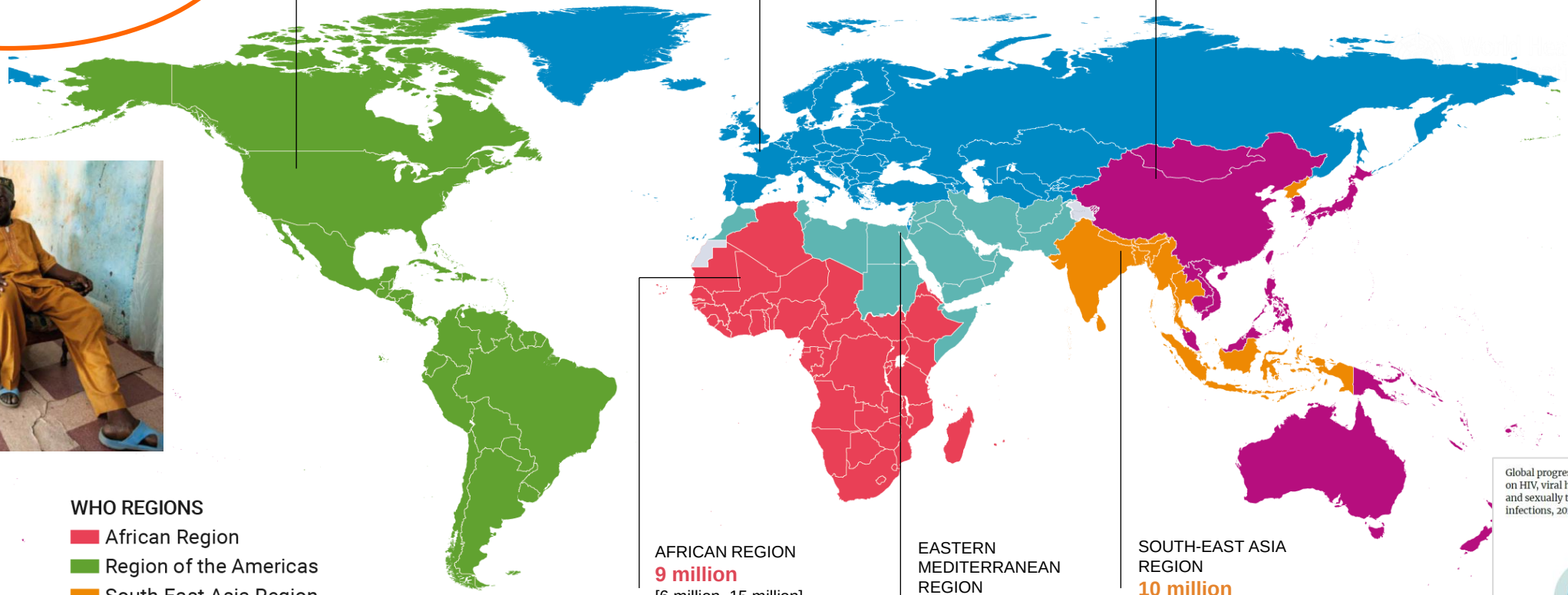
Burden of chronic hepatitis C viraemic infection by WHO Region, 2019

GLOBAL
58 million
[46 million–76 million]

REGION OF THE AMERICAS
5 million
[4 million–5 million]

EUROPEAN REGION
12 million
[10 million–14 million]

WESTERN PACIFIC REGION
10 million
[8 million–14 million]

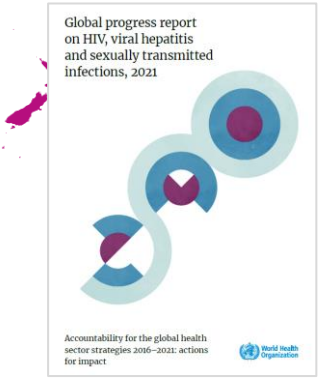


AFRICAN REGION
9 million
[6 million–15 million]

EASTERN MEDITERRANEAN REGION
12 million
[10 million–13 million]

SOUTH-EAST ASIA REGION
10 million
[8 million–19 million]

WHO REGIONS
- African Region
- Region of the Americas
- South-East Asia Region
- European Region
- Eastern Mediterranean Region
- Western Pacific Region
- Not applicable



Global Progress Report on HIV, viral hepatitis and STIs, 2021, WHO HQ

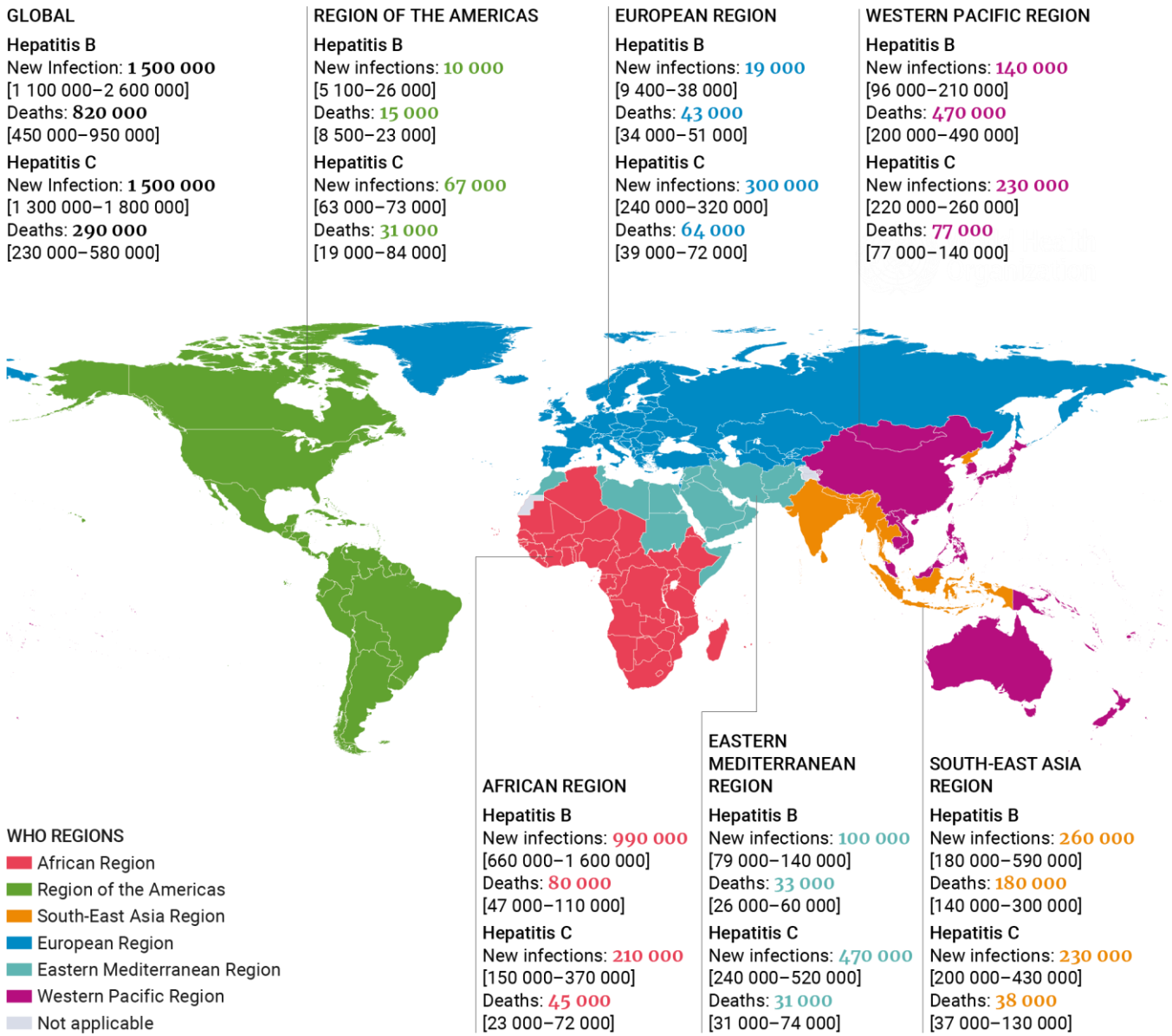
New 2021 WHO Global Progress Report (Hepatitis B and C)

New 2019 data on Incidence, burden, mortality, testing/treatment cascade

Viral Hepatitis

New data on Incidence, prevalence and mortality, testing and treatment cascade

- **3.0 million new HCV & HBV infections**
  - **1.5 million new HCV infections**
- **1.1 million HCV & HBV deaths with initial signs of HCV declines (290,000 deaths)**
- **9.4 million people receiving HCV treatment (9-fold increase from 1 million baseline in 2015)**

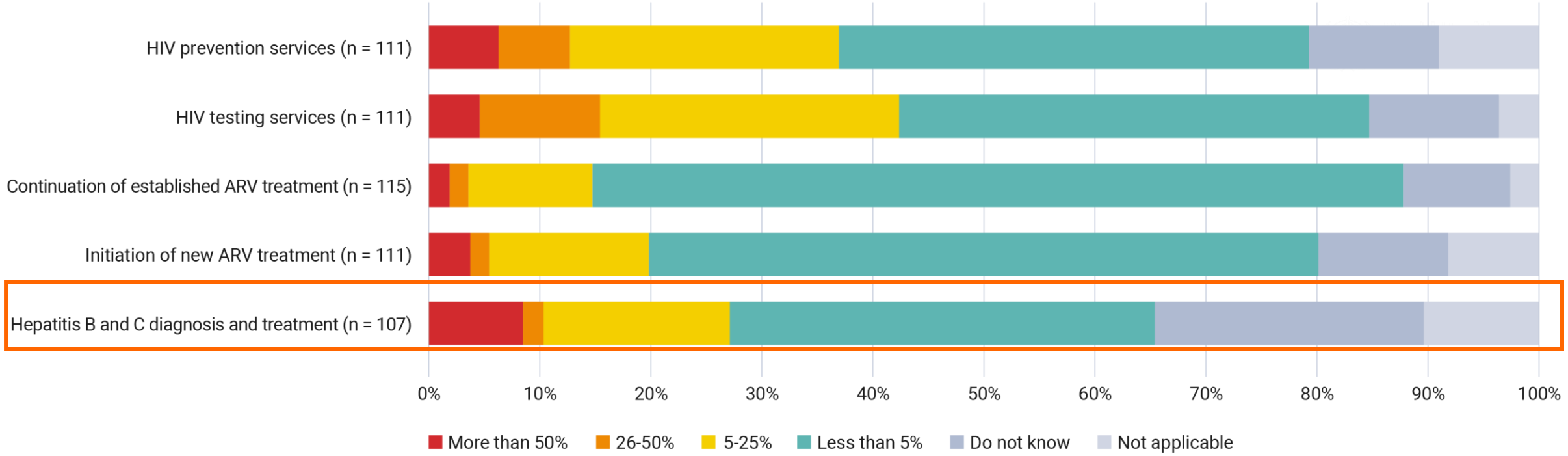


Vulnerable populations

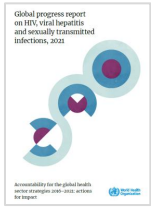
- Globally, 11.3 Million current PWID [1,2] *(World Drug Report, 2019)*
- 39.4% viremic HCV infections among PWID [1,2] *(Grebely et al., Addiction, 2019)*
- HCV affects 2–15% of people living with HIV, accounting for 2.75 million - of whom 1.3 millions are PWID (WHO)
- **23% - 39% of new HCV infections *(Degenhardt L et al. Lancet Global Health. 2017 and Trickey et al. Lancet Gastro Hep, 2019)***
- 1 in 3 HCV deaths are attributable to injecting drug use globally *(Degenhardt L et al. Lancet Global Health. 2017)*
- ***High prevalence and incidence rates among MSM (specifically living with HIV and PrEP users) globally (Jin et al. Lancet GH 2020)***

COVID-19 Disruptions of Hepatitis Diagnosis & Treatment Services

Disruption in other services for HIV and viral hepatitis, March 2021

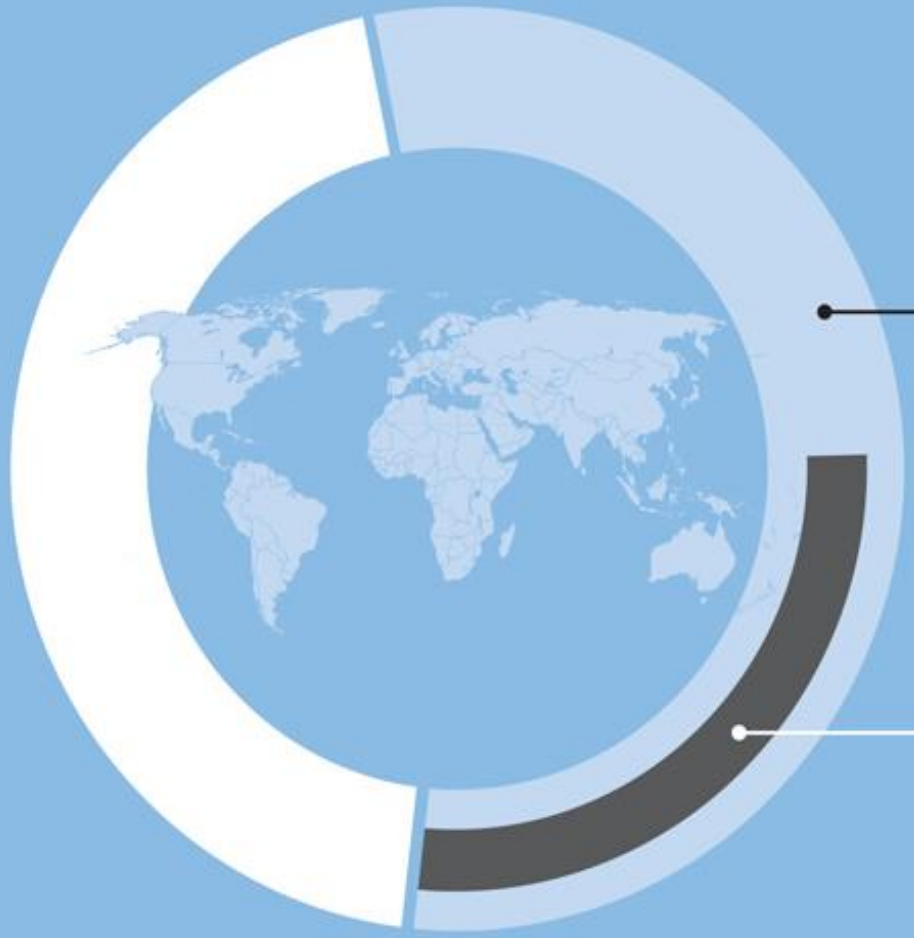


Global Progress Report on HIV, viral hepatitis and STIs, 2021, WHO HQ



COVID-19

OPIOID AGONIST THERAPY (OAT)



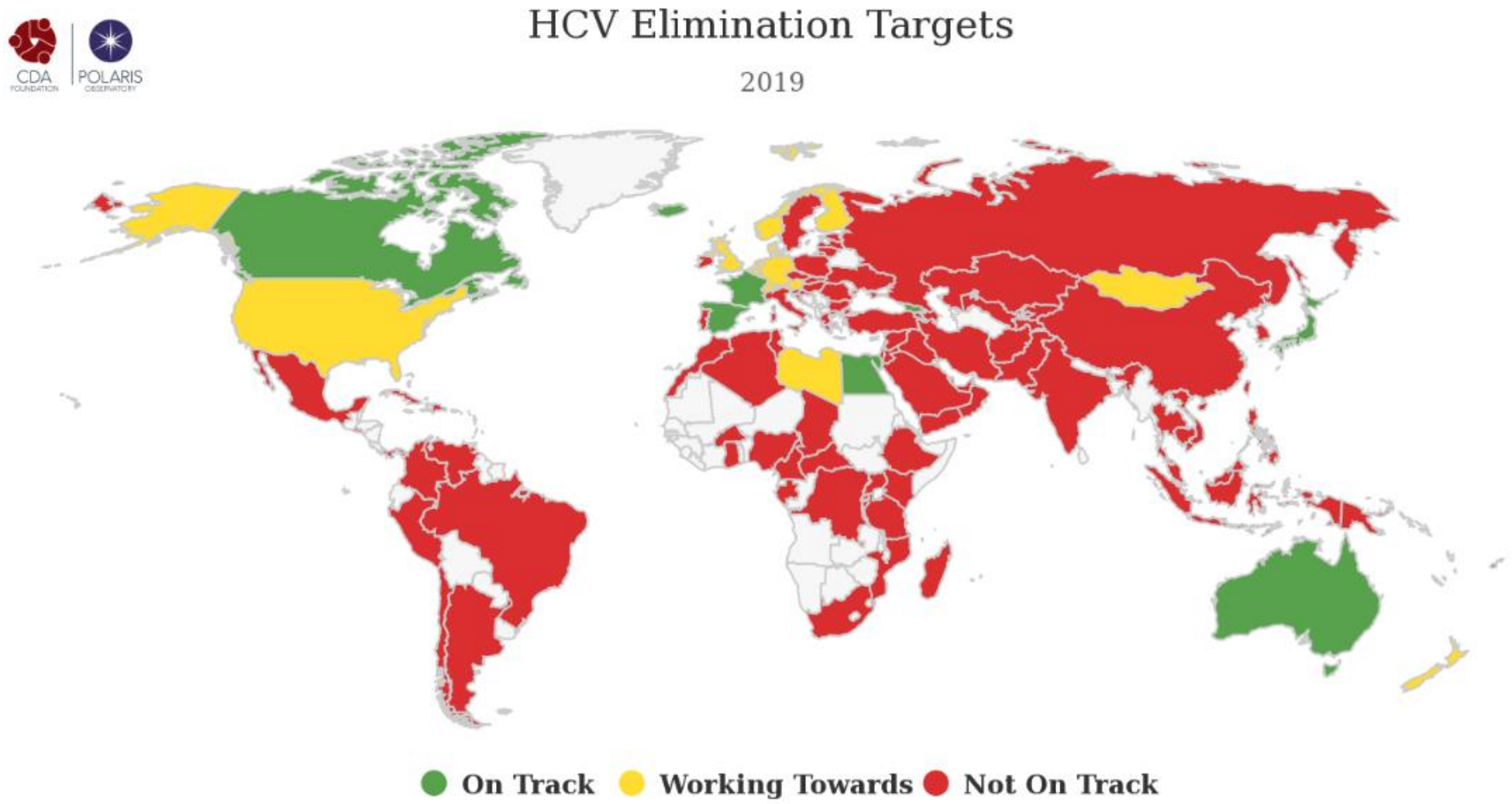
84 COUNTRIES WORLDWIDE PROVIDE OAT

47 COUNTRIES (WITH AT LEAST ONE COUNTRY IN EVERY REGION) EXPANDED TAKE-HOME CAPACITIES PROVIDING FOR LONGER TAKE-HOME PERIODS

23 COUNTRIES MADE DISTRIBUTION MORE ACCESSIBLE WITH HOME DELIVERY OF OAT MEDICATION, OFFERING DOSING AT COMMUNITY PHARMACIES, OR DISTRIBUTING OAT IN OUTREACH SETTINGS

HARM REDUCTION INTERNATIONAL

8 countries are expected to achieve the HCV targets by 2030



Slide courtesy Homie Razavi; CDA Foundation; 2021

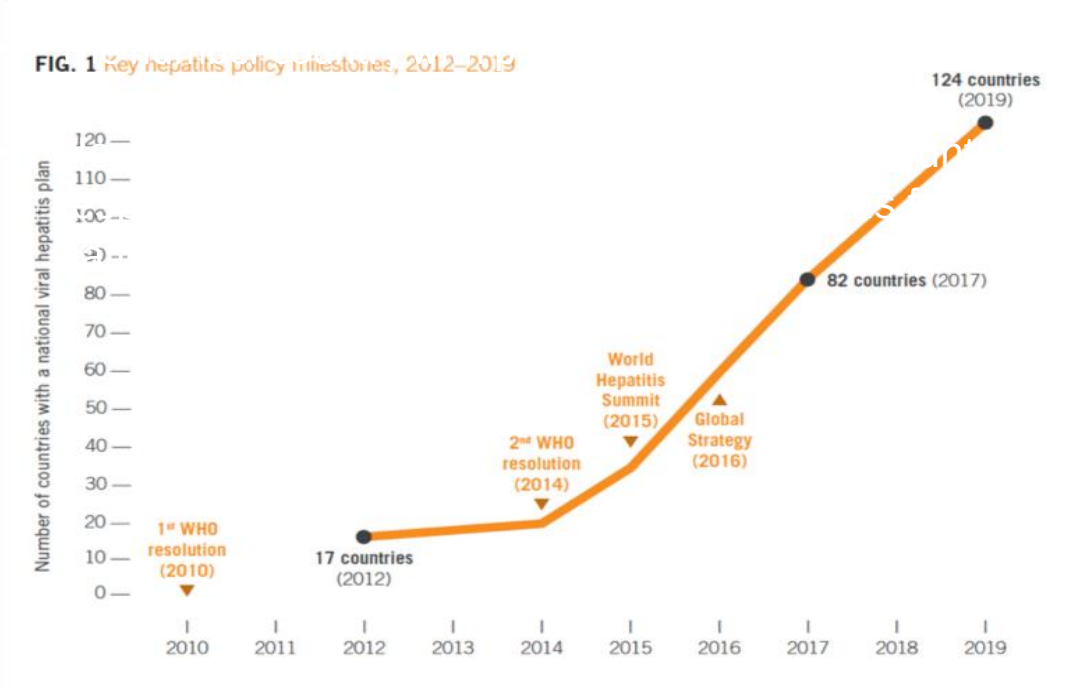
What are the 5 core barriers?

Policies

CRITICAL ENABLERS	
1	**Laws, policies and practices** should be **reviewed** and, where necessary, revised by policy-makers and government leaders, with meaningful engagement of stakeholders from key population groups, to allow and support the implementation and scale-up of health-care services for key populations.
2	Countries should work towards implementing and enforcing **antidiscrimination and protective laws**, derived from human rights standards, to eliminate stigma, discrimination and violence against people from key populations.
3	**Health services** should be made **available, accessible and acceptable** to key populations, based on the principles of medical ethics, avoidance of stigma, non-discrimination and the right to health.
4	Programmes should work toward implementing a package of interventions to **enhance community empowerment** among key populations.
5	**Violence** against people from key populations should be prevented and addressed in partnership with key population-led organizations. All violence against people from key populations should be monitored and reported, and redress mechanisms should be established to provide justice.

Consolodiated KP guidelines, WHO, 2016; Geneva

HCV and PWID: Policy review (2019)



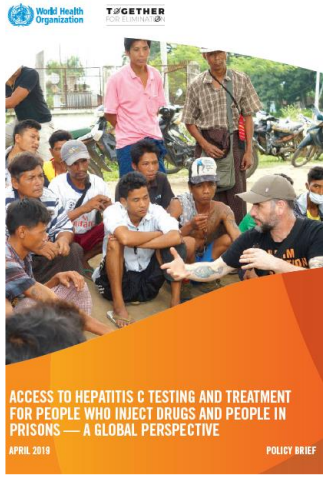


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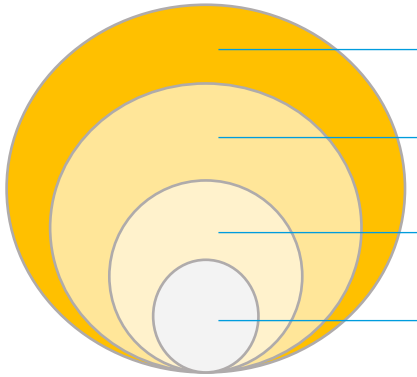
Fig. 2. Number of countries with hepatitis plans

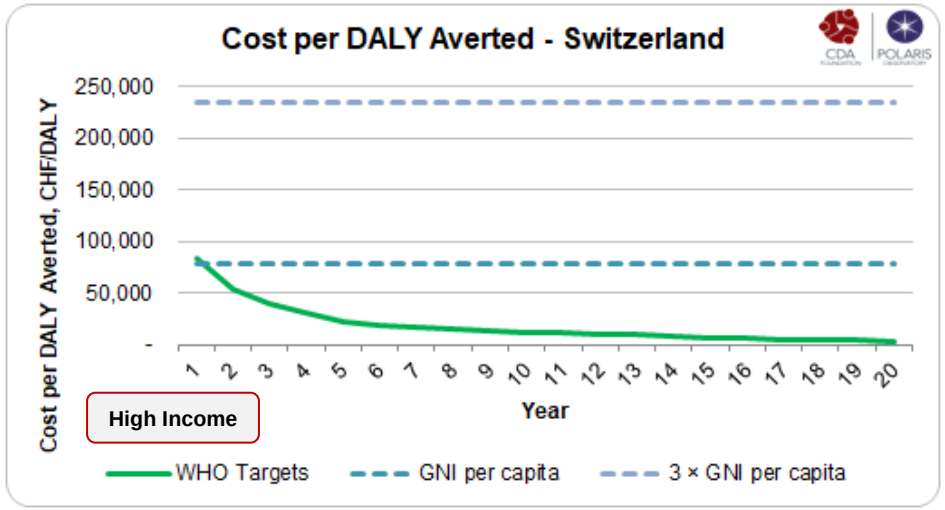


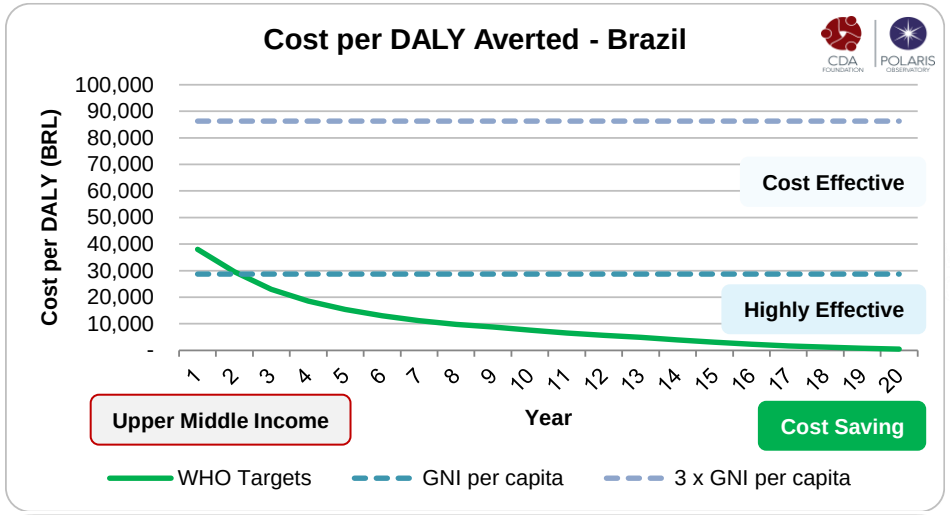
- Total number of hepatitis plans: 124
- Country plans accessed: 81
- Country plans with interventions for PWID: 51
- Country plans with interventions for people in prisons: 28

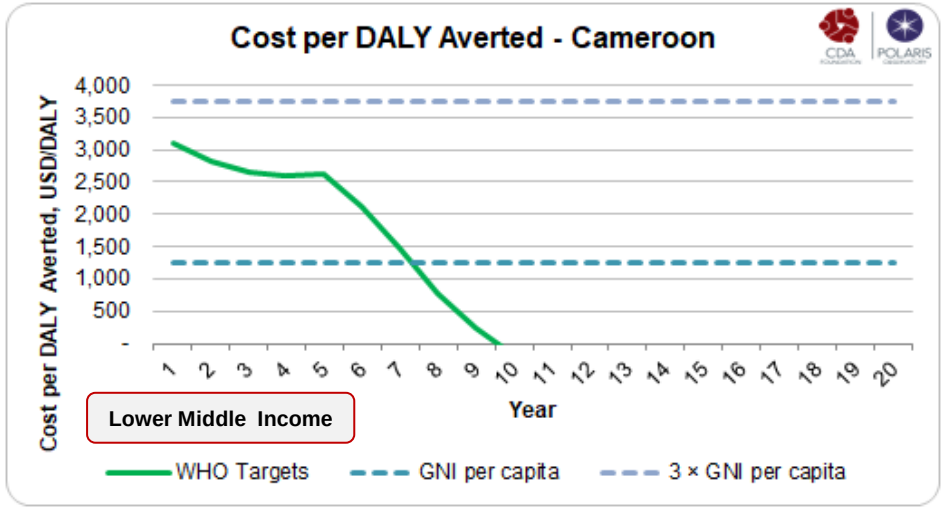
Access to HCV Testing and Treatment for PWID and people in prisons; Policy Brief; WHO HQ 2019

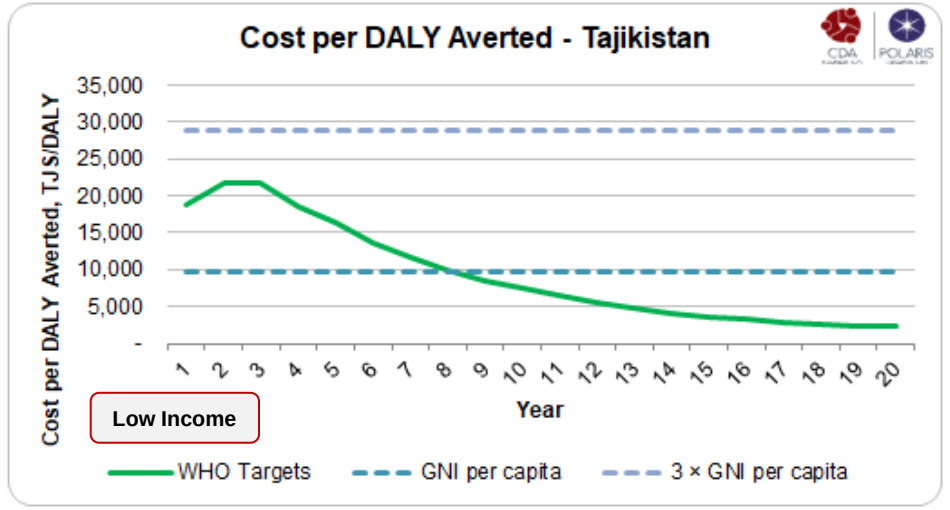
Financing

Elimination of hepatitis C virus (HCV) is highly cost effective or cost saving in all countries we have studied









Slide courtesy Homie Razavi; CDA Foundation; 2021

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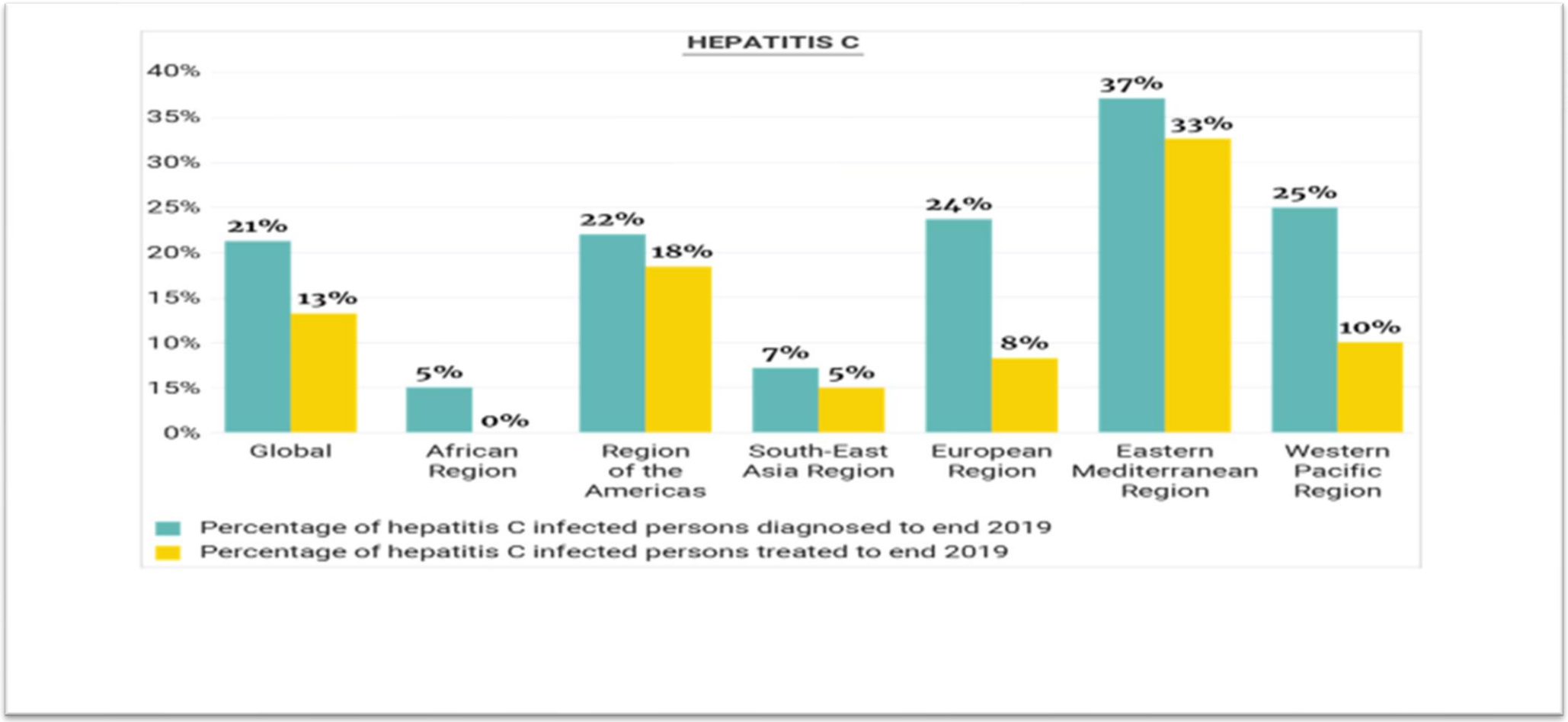
Access

Only 21% of estimated 58 million people with chronic HCV infection were diagnosed in 2019 with variation by regions



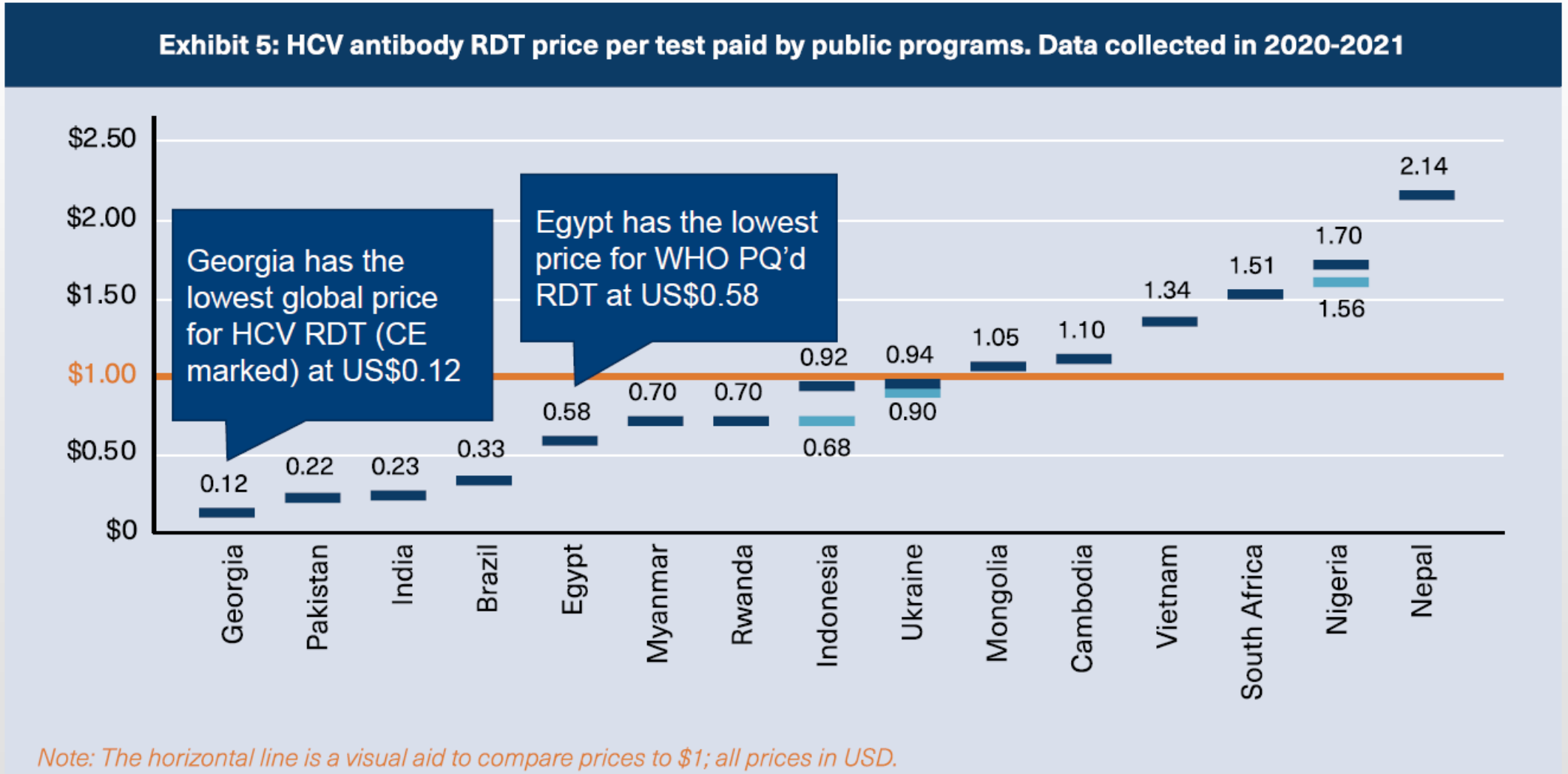
Global Progress Report on HIV, viral hepatitis and STIs, 2021, WHO HQ

Total number of low-income, lower-middle-income and upper-middle-income countries with registered DAAs, 2017 and 2019

DAAs	2017			2019		
	Countries with generic sources registered	Countries with originator sources registered	Total number of countries with registered sources	Countries with generic sources registered	Countries with originator sources registered	Total number of countries with registered sources
Daclatasvir	2	10	12	16 (+ additional 16 as of March 2020)	14	30
Sofosbuvir	23	31	54	29	32	61
Sofosbuvir + daclatasvir	1	14	15	10	17	27
Sofosbuvir/ledipasvir	5	24	29	15	36	51
Sofosbuvir/ velpatasvir	1	2	3	6	28	34

Data source: Report of the WHO survey on access to DAAs, 2019 and Medicines Patent Pool, 2020[42]

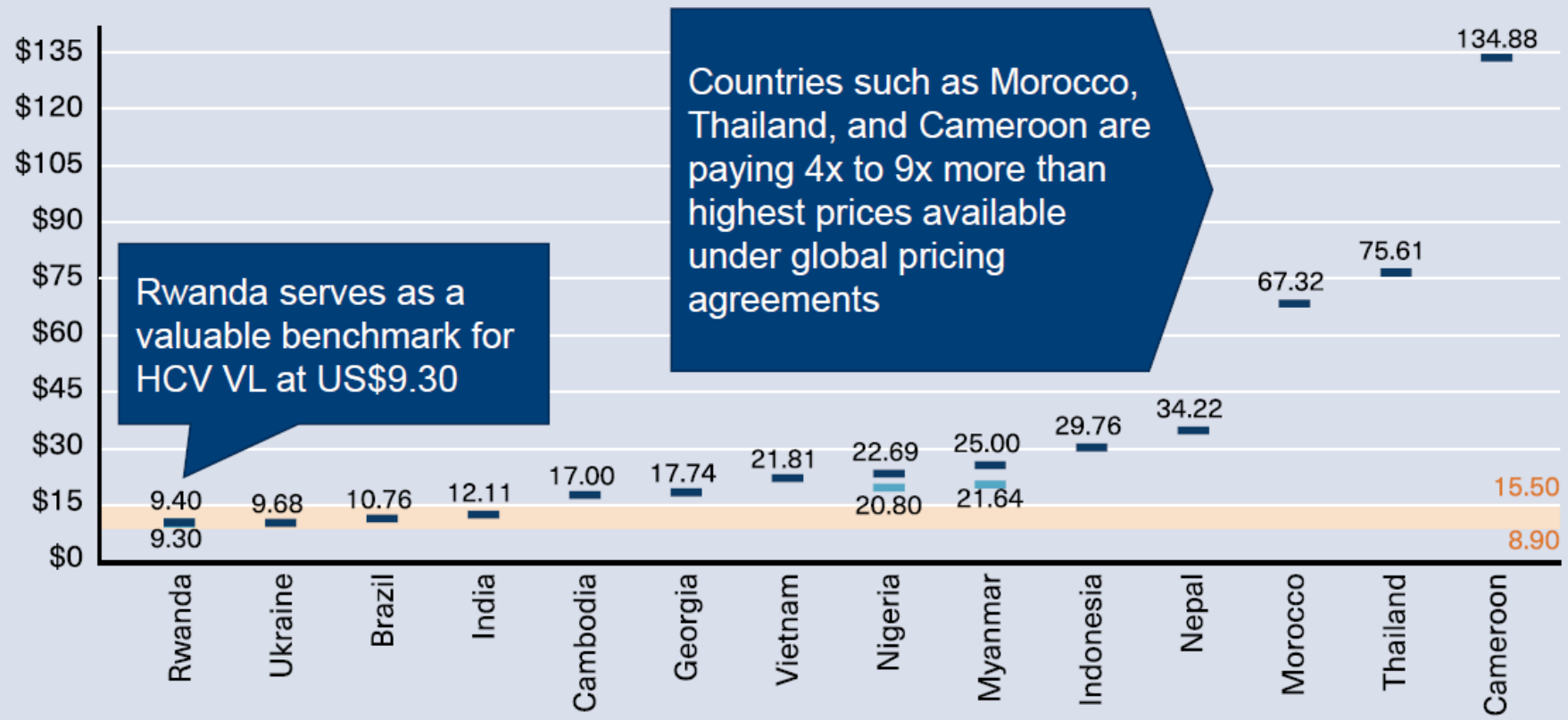
Screening: Many countries are accessing RDTs at lower than US$ 1, setting a benchmark for other programs to target



Slide courtesy CHAI; 2021

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.

Slide courtesy CHAI; 2021

Harm Reduction Coverage and PWID care

What is required to achieve the WHO's HCV elimination targets in countries with concentrated epidemics?

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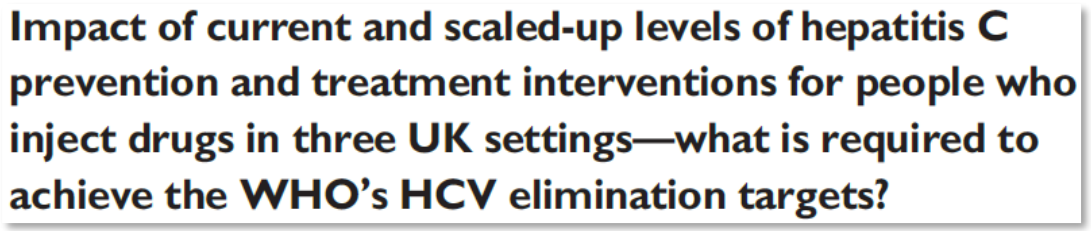
Impact of current and scaled-up levels of hepatitis C prevention and treatment interventions for people who inject drugs in three UK settings—what is required to achieve the WHO's HCV elimination targets?


Scaling up prevention and treatment towards the elimination of hepatitis C: a global mathematical model

Alastair Hefferman, Graham S Cooke, Shevanthi Nayagam, Mark Thursz, Timothy B Hallett

Scaling up high-coverage needle and syringe provision + opioid substitution therapy + effective HCV treatment would reduce the incidence of HCV infection by 90% by 2030.

Ward Z et al. Impact of current and scaled-up levels of hepatitis C prevention and treatment interventions for people who inject drugs in three UK settings – what is required to achieve the WHO's HCV elimination targets? Addiction, Sep 2018

By 2030, interventions that reduce risk of transmission in non-PWID by 80% and increase coverage of harm reduction services to 40% of PWID could avert 14·1 million (95% credible interval 13·0–15·2) new infections.

Heffernan A, Cooke GS, Nayagam S, Thursz M, Hallett TB. Scaling up prevention and treatment towards the elimination of hepatitis C: a global mathematical model. Lancet (London, England). 2019.

HARM REDUCTION IMPLEMENTATION HAS WORSENED SINCE OUR LAST REPORT IN 2018, AFTER HAVING STALLED SINCE 2014.

THE NUMBER OF COUNTRIES WHERE NEEDLE AND SYRINGE PROGRAMMES ARE AVAILABLE REMAINED LEVEL

THE NUMBER OF COUNTRIES WHERE OPIOID AGONIST THERAPY IS AVAILABLE DECREASED BY TWO

"Harm reduction programs constitute a gate-way to enable access to health care. This is an essential entry-point into the HCV cascade of care for severely marginalized and stigmatized communities." Ernst Wisse; Medecins du Monde

HARM REDUCTION INTERNATIONAL

What are the 4 core opportunities ?

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Integration

Vision, goals and strategic directions of the Global Health Sector Strategies 2022-2030

A common vision

End epidemics and advance universal health coverage, primary health care and health security

Disease goals

By 2030,
- **End AIDS epidemic as a public health threat**
- **Eliminate viral hepatitis as a public health threat**
- **End sexually transmitted infections as public health concerns**

Strategic Directions

with ***shared*** *and* ***disease-specific actions***

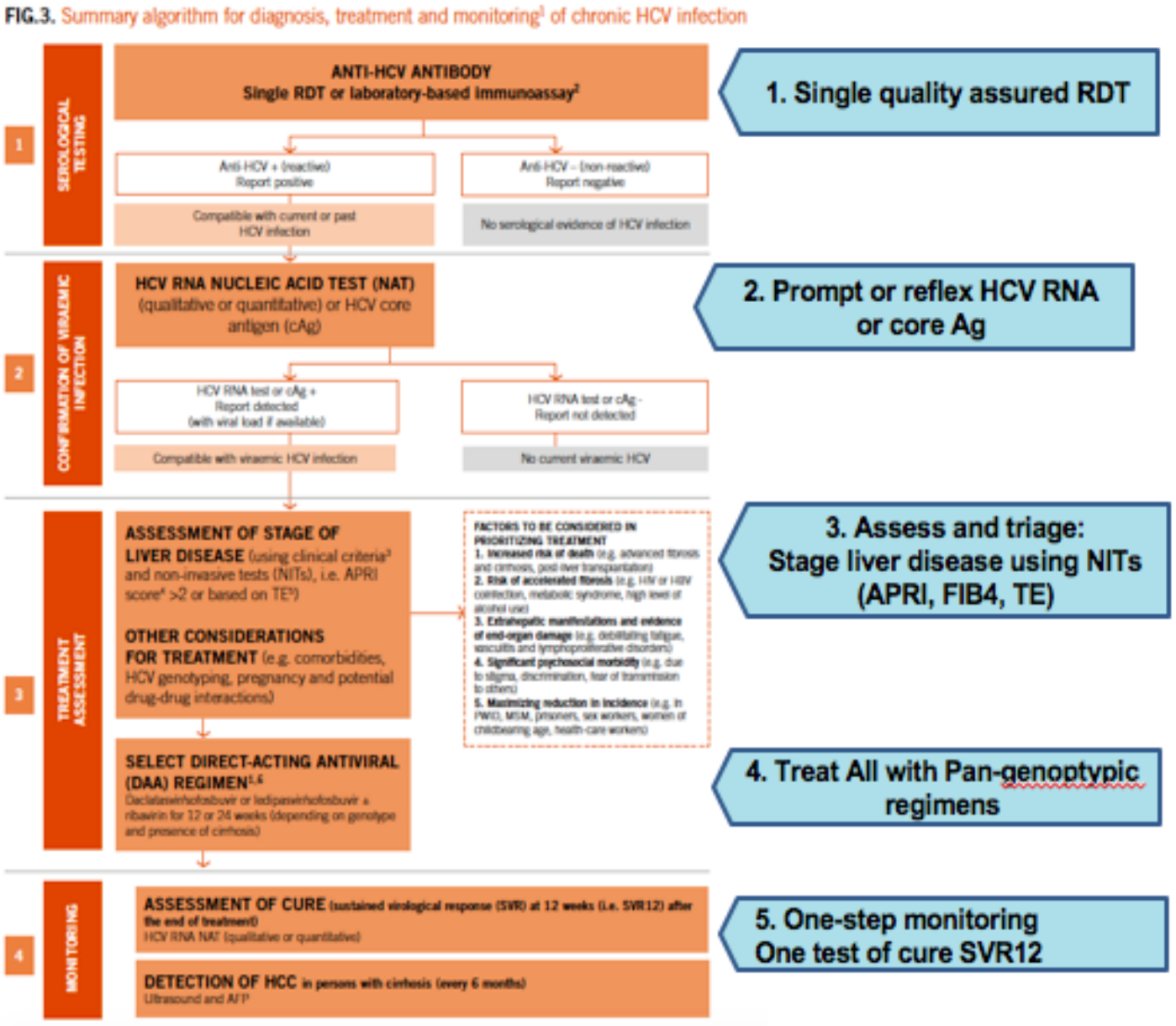
	HIV strategy	Viral hepatitis strategy	Sexually transmitted infections strategy
SD1. Deliver people-centered evidence-based services			
SD2. Optimize systems, sectors and partnerships for impact			
SD3. Generate and use data to drive decisions for action			
SD4. Engage empowered communities and civil society			
SD5. Foster innovation for accelerated action			

Drivers of progress

Gender, equity, and human rights
Funding
Leadership and partnership

Decentralized and person-centred care

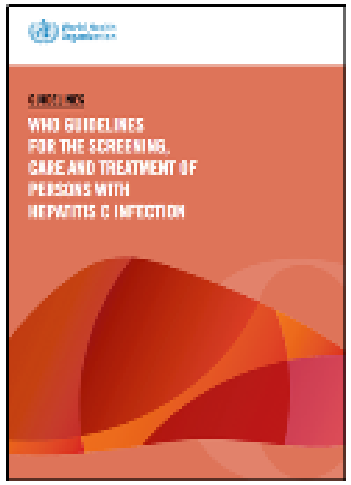
Simplified and standardized HCV testing and management algorithm



Five key steps

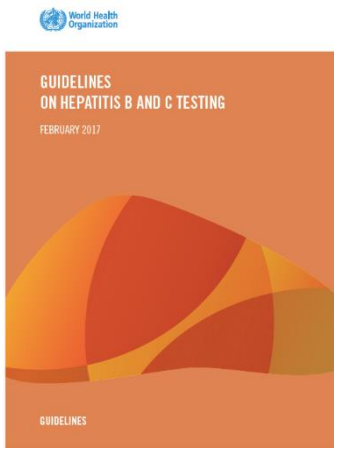
2017 WHO Guidelines on hepatitis B and C testing

New Directions - Updating WHO global guidelines



HCV treatment:

- Simplified service delivery: decentralization, integration and task-sharing
- Vulnerable populations: Peer navigation
- Treatment of recently acquired infection (people at ongoing risks)



Testing:

- HCV Self-testing
- Retesting NAT/Core Ag 3-6 monthly for people with ongoing risk
- Use of PoC viral load
- Dried Blood spots

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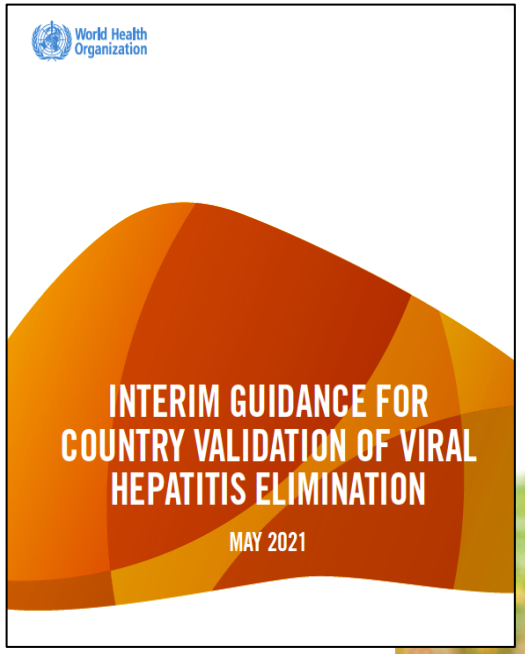
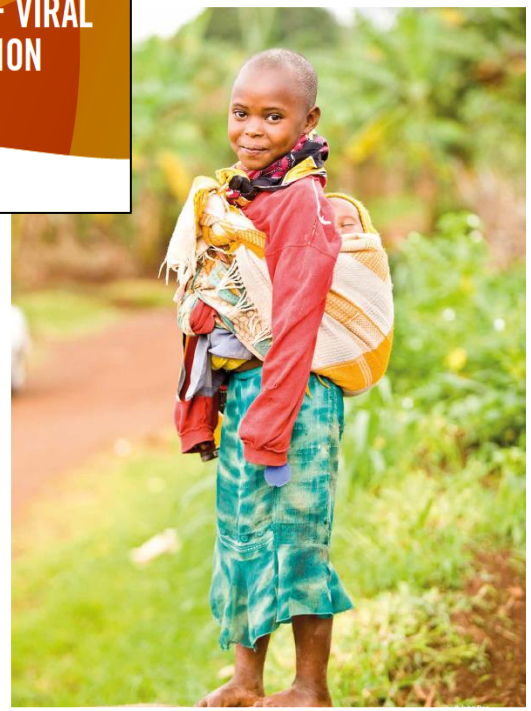
Elimination

Interim Guidance for the country validation of viral hepatitis elimination – May 2021





Summary Impact and programmatic targets for country validation of elimination

Elimination targets	Elimination of chronic HBV infection as a public health problem		Elimination of chronic HCV infection as a public health problem	
2030 GHSS relative reduction reference targets (compared to 2015)	**Incidence** 95% reduction	**Mortality** 65% reduction	**Incidence** 80% reduction	**Mortality** 65% reduction
HBV- and HCV- specific absolute prevalence, incidence and mortality targets	**HBV EMTCT** ≤0.1% HBsAg prevalence in ≤5 year - olds[a,b]	**Annual mortality**[f] (HBV) ≤4/100 000	**Annual incidence** (HCV) ≤5/100 000 ≤2/100 (PWID)	**Annual mortality**[f] (HCV) ≤2/100 000
Programmatic targets[a]	**Countries with universal HBV vaccine birth dose (BD)** ≥90% HepB3 vaccine coverage ≥90% HepB timely hepatitis B BD (HepB-BD) coverage[d] **Countries with targeted HBV vaccine birth dose (BD)** ≥90% HepB3 vaccine coverage ≥90% coverage of those infants at risk with timely targeted HepB-BD ≥90% coverage of maternal antenatal HBsAg testing ≥90% coverage with antivirals for those eligible[h] *Additional target:* ≤2% MTCT rate[c]	**Testing and treatment** ≥90% people with HBV diagnosed ≥80% of people diagnosed with HBV and eligible for treatment are treated[g] **Prevention** ≥90% HepB3 vaccine coverage ≥90% HepB-BD coverage 0% unsafe injections 100% blood safety	**Testing and treatment** ≥90% people with HCV diagnosed ≥80% of people diagnosed with HCV are treated[g] **Prevention** 0% unsafe injections 100% blood safety 300 needles/syringes/PWID/year	

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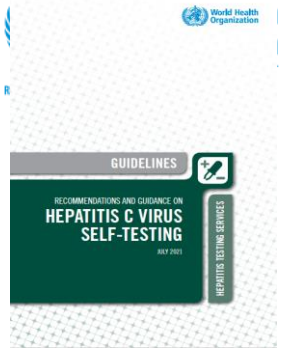
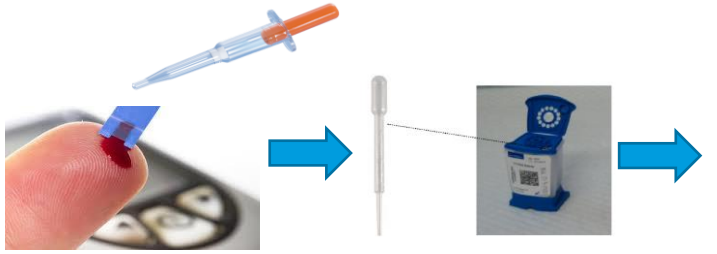
Innovations

Diagnostic Innovations and Opportunities

1. HCV self-testing
2. Role of point-of-care HCV viral load in improving linkage
3. Dried blood spots specimens for viral load ±serology
4. Diagnostic integration - Use of integrated multi-disease platforms (HIV, HCV RNA and HBV DNA)
5. Low cost HCV core Antigen RDT for confirmation of viraemic infection



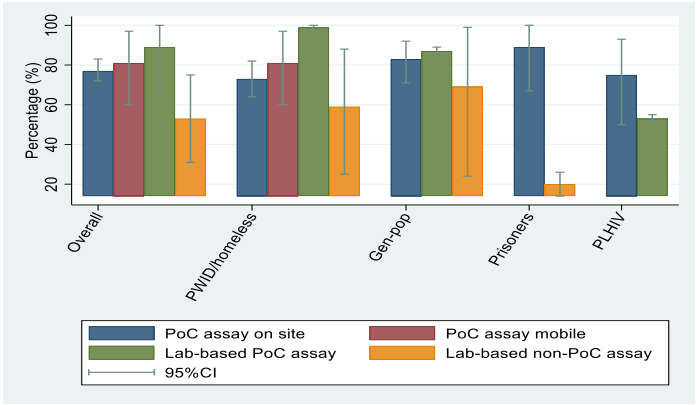
Minivette capillary tube



Finger-prick

Single-use test cartridge

GeneXpert machine



- We have a clear strategy and targets, and we have the tools: elimination is possible
- Huge funding gaps in HCV elimination
- COVID-19 disruptions have been important
- Addressing HCV in vulnerable populations is key
- Harm reduction and legal policy reform are the backbone for HCV elimination in PWID : there is a huge gap in LMICs
- Decentralized and integrated care is a huge opportunity