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Section 9: Tackling the Hepatitis C epidemic: a global landscape

Céline Grillon (Médecins du Monde)

Training "Hepatitis C and HR for PWUD",

19th-24th Sept. 2016, Nairobi, Kenya

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Learning objective of the session: Identifying key elements of the global landscape regarding access to hepatitis C prevention, diagnosis and treatment



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Outline of the presentation

- Global policies related to hepatitis C
- 2. The access challenge
- 3. The funding gap





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PART 1: GLOBAL POLICIES RELATED TO HEPATITIS C



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The World Health Organization (WHO) is a specialized agency of the United Nations that is concerned with international public health

WHO's role in public health

- » providing leadership
- setting norms and standards
- providing technical support

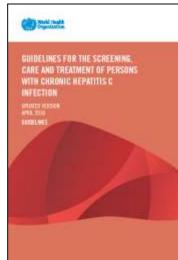
Once a year, WHO member states meet during the <u>World</u> <u>Health Assembly</u> to discuss and adopt strategic orientations and policies

WHO has also regional Committees

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WHO and Hepatitis C

- May 2014: World Health Assembly adopts a Resolution on viral hepatitis that urges member states « to develop and implement coordinated multisectoral national strategies for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context »
- April 2014 : WHO Guidelines for the screening, care and treatment of persons with hepatitis C infection (updated in April 2016)







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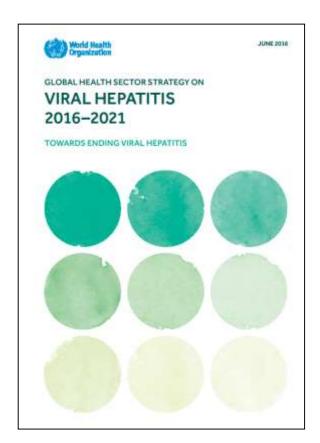
May 2016: World Health Assembly adopts the Global Health Sector ____
Strategies for viral hepatitis, 2016-2021

GLOBAL VISION

A world where viral hepatitis transmission is halted and everyone living with viral hepatitis has access to safe, affordable and effective prevention, care and treatment services.

GOAL

Eliminate viral hepatitis as a major public health threat by 2030.*







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WHO Global Health Sector Strategies for viral hepatitis, 2016-2021 (1/3)

TARGET AREA	BASELINE 2015	2020 TARGETS	2030 TARGETS
Impact targets			
Incidence: New cases of chronic viral hepatitis B and C infections	Between 6 and 10 million infections are reduced to 0.9 million infections by 2030 (95% decline in hepatitis B virus infections, 80% decline in hepatitis C virus infections)	30% reduction	90% reduction
		(equivalent to 1% prevalence of HBsAg ^a among children)	(equivalent to 0.1% prevalence of HBsAg among children) ¹⁶
Mortality: Viral hepatitis B and C deaths	1.4 million deaths reduced to less than 500 000 by 2030 (65% for both viral hepatitis B and C)	10% reduction	65% reduction





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WHO Global Health Sector Strategies for viral hepatitis, 2016-2021 (2/3)

TARGET AREA	BASELINE 2015	2020 TARGETS	2030 TARGETS	
Service coverage targets		<u>.</u>	100, 100,	
Blood safety	39 countries do not routinely test all blood donations for transfusion-transmissible infections 89% of donations screened in a quality-assured manner ¹²	95% of donations screened in a quality- assured manner	100% of donations are screened in a quality- assured manner	
Safe injections: percentage of injections administered with safety-engineered devices in and out of health facilities	5%	50%	90%	
Harm reduction: number of sterile needles and syringes provided per person who injects drugs per year	20	200	300	
Viral hepatitis B and C <5% of chronic hepatitis infection diagnosed		30%	90%	
Viral hepatitis B and C treatment	<1% receiving treatment	5 million people will be receiving hepatitis B virus treatment	80% of eligible persons with chronic hepatitis B virus infection treated	
		3 million people have received hepatitis C virus treatment (Both targets are cumulative by 2020)	80% of eligible persons with chronic hepatitis C virus infection treated	





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WHO Global Health Sector Strategies for viral hepatitis, 2016-2021 (3/3)

Providing harm reduction services

A package of harm reduction services for people who inject drugs can be highly effective in preventing the transmission and acquisition of viral hepatitis A, B and C, as well as HIV and other blood-borne infections. Such a package should be integrated into a comprehensive set of services for the prevention and management of substance use disorders. WHO, UNODC and UNAIDS have defined a set of inserventions and services that should be included in a comprehensive package for people who inject drugs. It Included in the package are five intervention areas that will have greatest impact on hepatitis epidemics: steelle needle and syringe programmes, opoid substitution therapy for opioid users, risk reduction communication, hepatitis B vaccination, and treatment of chronic hepatitis infection.

The hepatiris C virus is more easily transmissible than HIV, therefore harm reduction services should include provision of all injecting paraphernalia, including mixing containers and solutions. This hepatith strategy calls for a major increase in provision of sterile needles and syringes to people who inject drugs, from an estimated baseline of 20 needles and syringes per person who injects drugs per year to 200 by 2020 and 300 by 2030. Current coverage of these interventions is too low to have a significant impact on bepatitis epidemics. Ensuring sufficient coverage of other harm reduction interventions depends on overcoming legal and societal barriers.

HARM REDUCTION

PRIORITY ACTIONS FOR COUNTRIES

implement a comprehensive package of harm reduction services, where appropriate, based on the WHO package of audience-based harm reduction interventions for people who riject drugs. Taking into account the domestic context, legislation and jurisdictional responsibilities.

Address legal and institutional barriers to the provision of harm reduction services.

Link hepatitis and harm reduction services to facilitate integrated prevention, treatment and care for people who use drugs.

PRIORITY ACTIONS FOR WHO

Develop and update policies and guidance on evidence-based prevention and management, of enal hepatitis B and C infection for people who inject drugs and for non-injecting drugusers, including people who use cocaine and amphitamine-type stimulants.

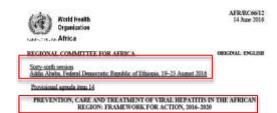
Provide advocacy and technical support to countries to mobilize commitment and resources for recommended harm reduction interventions.





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Prevention, Care and Treatment of Viral Hepatitis in the African Region: Framework for Action, 2016–2020



Report of the Secretarian

- Viral lepotitu is a lightly endemac disease and a poblic health problem. It is responsible for an estimated 1.4 mallon deaths per year globally, mostly then bepatitu-estated liver cancer and carbonic. Unfortunately, mostly people with chemic viral lepotitis are not aware of their status and do not receive appropriate transferant.
- 2. The World Heelth Assembly and the Regional Committee resolutions on wind hepatita fast were adopted in 2010 and 2014 respectively recognized until hapatite at a public leading problem and the used for government and populations to take action to prevent, disgnossand treat that hepatitis. The resolutions outliquio WEIO to provide the necessary technical import to enable Member States to develop robust national viral hapatitis prevention, diagnosis and becomes studieses.
- 3. Significant barriers, including madeignate data for making decinions and limited coverings of effective presention instructions, used to be addressed before the goal of elimanating value highests as a sugary public health these time be enabled. The lack of single and effective highests thetaig strategies and tools, the very limited account to effective technical and once services, unaffordable hepitelin medicates and diagnostics, and lack of a comprehensive public health approach need to be addressed as well. Various effective three technical and the contractive evidential and previous equalities account to well. Various efficiency and decrementation hander access to health services for populations that may be inorginalized and who are at larger rins of beginning uniform.
- 4. The size of the document, Prevention, Case and Treatment of viral hepotita in the African Region. Framework for action 3916-2002 is to guide Measure States in the African Region in unplement the Global Hoofts. Sector Strategy on viral hepotita. The proceed actions proposed include developing data volcens to understand the bourder of the documents of the Company of the Comp
- 5. This financework defines the response to varia bepatitis in the Region for the period 20th-2000 as a construction to achieving the 2000 agends for naturable development by manazing unreceived landship coverage. Strengthering health systems and prioritizing amoretion will be causal to achieving the targets set in the Regional Statiety. In a proposed that the activation to achieving the targets set may be a first the received natural restrictions. Furthermore, participation of all stakeholders, archaeling communities, incide the lendership of governments. And the essential.
- 8. The Regional Committee is invited to examine and adopt this Euroework.

Adopted by WHO Regional Committee for Africa on 21st August 2016 to guide Member States in the African Region to implement the Global Health Sector Strategy on viral hepatitis.

"By 2020, all 47 countries of WHO AFRO have developed <u>national action plans for the prevention</u>, care and treatment of viral <u>hepatitis</u>"



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UN Sustainable Development Goals

On September 25th 2015, countries adopted a set of goals to **end poverty**, **protect the planet**, and **ensure prosperity for all** as part of a <u>new sustainable development agenda</u>.



Each goal has specific targets to be achieved over the next 15 years.

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HOME ABOUT SECRETARY-GENERAL GOALS TAKE ACTION KEY DATES MEDIA WATCH AND LISTEN

Goal 3: Ensure healthy lives and promote well-being for all at all ages

Facts and figures Goal 3 targets Links

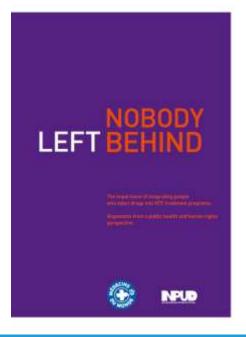
- By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births
- By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births
- By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases
- By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
- Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol
- By 2020, halve the number of global deaths and injuries from road traffic accidents
- By 2030, ensure universal access to sexual and reproductive health-care services, including for family planning, information and education, and the
 integration of reproductive health into national strategies and programmes
- Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective,



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Summary of the policies landscape

- Olobal dynamic to tackle hepatitis C epidemic
- Countries will start developing national action plans





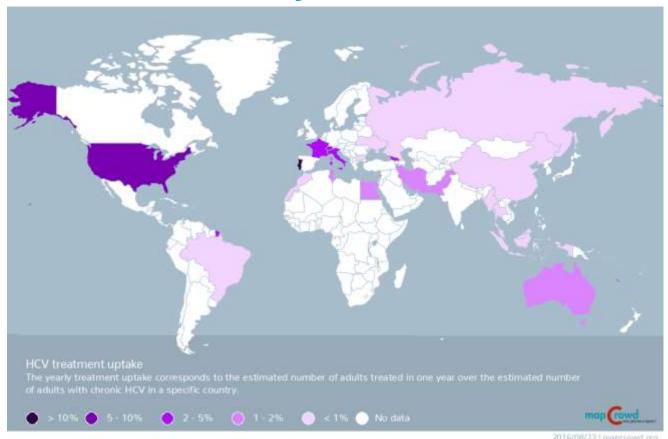


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PART 2: THE ACCESS CHALLENGE



Globally, access to hepatitis C treatment is very low

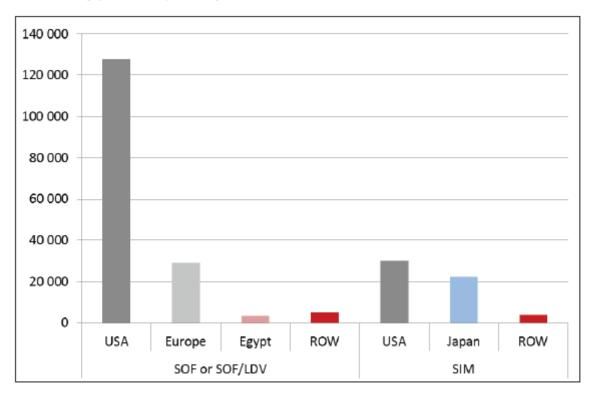






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Figure 6. Estimated number of people treated with SOF, SOF/LDV or SIM by region (Q4 2013–Q4 2014)



ROW, rest of world

Note: Sales of SOF and SIM in Q4 2013 represent less than 1.5% of their total sales over the period Q4 2014–Q4 2014. See Annex 6 for sources and methodology used to prepare these estimates.

Source: UNITAID Report: HEPATITIS C MEDICINES Technology and Market Landscape – Update 2015

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Access to medicine?

= 3 elements





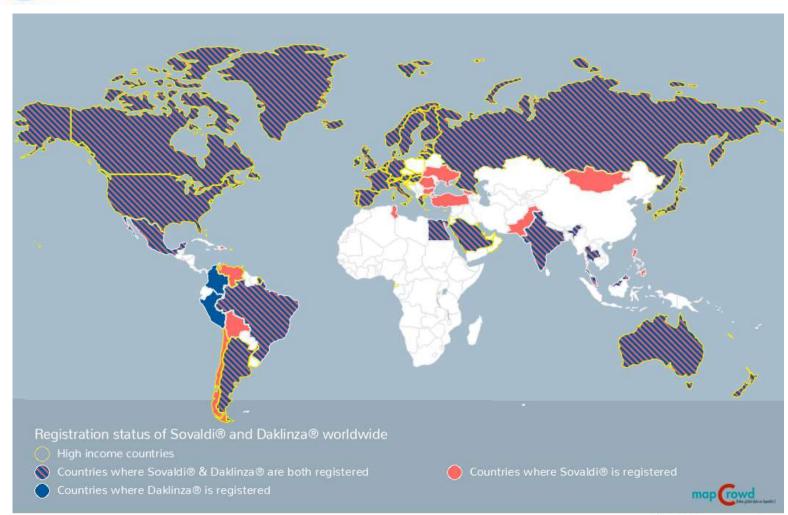
1) Availability

- Registration is a national procedure of reviewing the safety and efficacy of a new drug
- Certificate of Registration allows the drug to be legally marketed in the Country
- In Kenya, drugs are registered by the Pharmacy and Poisons Board (PPB)

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2) Affordability = price





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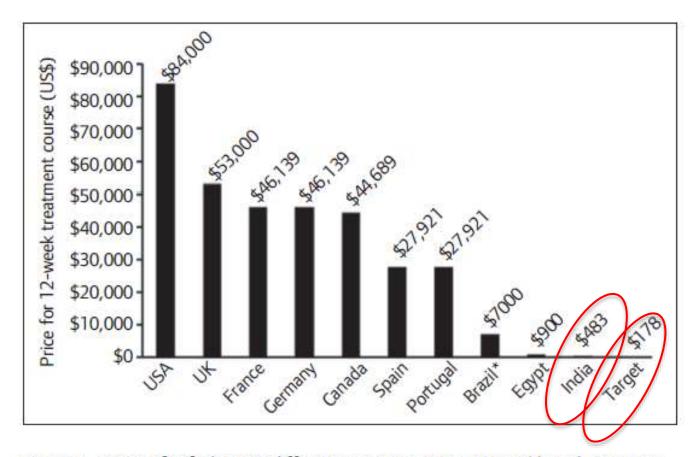


Figure 5. Prices of sofosbuvir in different countries. *Price in Brazil based on expert opinion

Source : Hill A, Simmons B, Gotham D, Fortunak J. Rapid reductions in prices for generic sofosbuvir and daclatasvir to treat hepatitis C. Journal of Virus Eradication 2016; 2: 28–31.

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Generic sofosbuvir availability and India market pricing as of 30 January 2016

	Marketing Company	Brand name	Gilead Licensee	Manufacturer	Printed price, USD*	Market price, USD*
1	Mylan Pharmaceuticals Private Limited	Sovaldi	N/A	Gilead Sciences	\$305	\$305
2	Biocon	Cimivir	Yes	Hetero Laboratories Limited	\$307	\$215
3	Dr Reddy's Laboratories	Resof	No	Hetero Laboratories Limited	\$308	\$215
4	Abbott India Limited	Viroclear	No	Hetero Laboratories Limited	\$323	\$192
5	Hetero Healthcare Limited	Sofovir	Yes	Hetero Laboratories Limited	\$299	\$185
6	Zydus Heptiza	SoviHep	Yes	Natco Pharma Limited	\$306	\$185
7	Cipla Limited	Hepcvir	Yes	Hetero Laboratories Limited	\$306	\$169
8	Mylan Pharmaceuticals Private Limited	МуНер	Yes	Natco Pharma Limited.	\$306	\$163
9	Emcure Pharmaceuticals Limited	Spegra	No	Natco Pharma Limited	\$306	\$154
10	Ranbaxy Laboratories	Sofab	Yes	Hetero Laboratories Limited	\$306	\$154
11	Natco Pharma Limited	Hansinst	V	Natco Pharma	- avenue	B
12	Strides Arcolab Limited	28 Tabi	ets (ATTENTION OF THE OWNER OWNER OF THE OWNER OWNE	Natco Pharma	T 20 h	Des V
13	Aurobindo Pharma	Sofosbuvir Table	e Managara	TBD	l adinomir 00	. 8
14	Laurus Laboratories	400 mg		TBD	Ledipasvir 90 m Sofosbuvir 400	mo 3
15	Sequent	Sofovir	2	TBD	lablets	W
16	Wockhardt Limited	सोफोवीर	Sofosbovir Tablets 400 mg	Natco Pharma	Ledifos	
*Prin	ed prices were obtained fro		Sofovir	ed on community	1029	æs in
	locations and through othe	32	4 USD	ne 28-pill bottl	517 US	SD
Rupe	es).	100000	2 weeks*		for 12 we	
rbd-	to be determined; N/A-not 🚚					



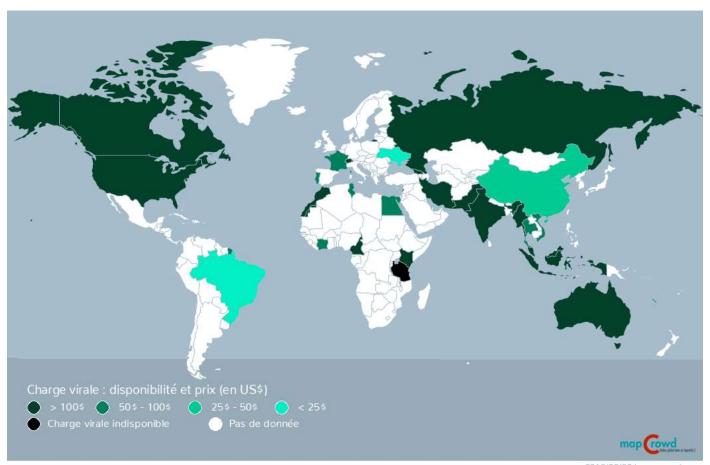
Source : TREATAsia,

http://www.amfar.org/treatasia.html

* Lowest price available in India (mapCrowd)



Affordability issue also concerns diagnosis





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3) Quality

- Ensuring bioequivalence of generic versions of DAAs
- In 2015 WHO expanded its prequalification program to HCV DAAs.
- No generic DAA prequalified yet



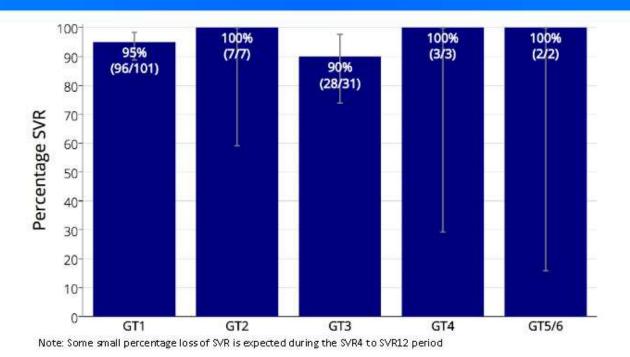
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» REDEMPTION-1 Study presented during International Liver Congress 2016: cure rates in branded medicines treatment and low-cost generic DAA treatment are very similar

REDEMPTION-1 Overall SVR4 Results For Generics



8

Summary of the policies landscape

Quality generic versions of HCV DAAs are available, and price are expected to further decrease;

But...

- DAAs are not yet registered in most LMICs
- Diagnosis test remains expensive

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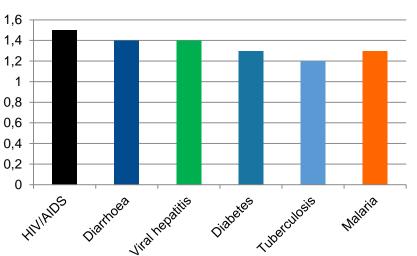
PART 3: THE FUNDING GAP



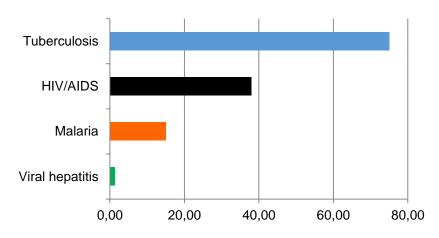
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- Viral hepatitis, the « silent epidemic » originally suffers from a lack of attention and funding
- No specific donor institution funding work on hepatitis
- Context of constraint due to economical crisis in donors contries

Number of deaths per diseases and per year 2010



WHO 2012 - Budget allocation compared to # of deaths



Source: In Lozano et al, Global Burden of Disease Study 2010 Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: a systematic analysis for the Global Burden of Disease Study 2010, Lancet 2012





- 2014 : <u>UNITAID</u> approved 2 grants to reduce barriers preventing access to new treatment of hepatitis C in low- and middle-income countries.
 - MSF grant to screen, diagnose and treat patients living with <u>HIV/HCV coinfection</u> in India, Iran, <u>Kenya</u>, Mozambique, Myanmar, and Ukraine to catalyse demand for newly-available medicines.
- **»** But...
 - Only for people living with HIV/HCV coinfection
 - UNITAID only finances <u>« demonstration interventions »</u>



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- April 2015: Global Fund Board approves a <u>new framework for financing co-infections and co-morbidities of HIV/AIDS</u>, tuberculosis and malaria (GF/B33/11) allowing countries to use some of their allocations to fund hepatitis C interventions
- Like UNITAID Global Fund is only considering hepatitis C under the approach of HIV/HCV coinfection
- But a substantive part of the investments required to develop access to HCV services (technical labs, training of physicians, procurement chains, etc.) could be done with this funding?

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Summary

- >> Limited international funding for hepatitis C. No specific funding mechanism to finance hepatitis C services scale up
- WHO strategy recommends the scale up towards universal health coverage. Need for increased public domestic funding (tax revenues and allocation of a greater share of government funds to health)
- Low- and lower middle-income countries will still rely on external funding to expand their hepatitis responses

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This presentation was produced with the financial support of the French development agency (AFD – Agence Française de développement). The ideas and opinions it contains are those of Médecins du Monde and do not necessarily represent those of AFD.