
2nd EU HCV Policy Summit

Securing sustainable funding for Hepatitis C Virus elimination plans



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Welcome and introduction



Chairs:

Prof. Angelos Hatzakis, Co-Chair, Hepatitis B&C Public Policy Association

Prof. Michael Manns, Co-Chair, Hepatitis B&C Public Policy Association



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1st EU HCV POLICY SUMMIT

Hepatitis C: The beginning of the end - key elements for successful European and national strategies to eliminate HCV in Europe



HCV Policy Summit, Brussels, 17 FEB 2016

Official presentation of the HCV Elimination Manifesto



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Endorsed by:



<http://www.hcvbrusselssummit.eu>



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Hepatitis C Elimination in Europe

“Our vision for a Hepatitis C-free Europe”

We, the signatories of this declaration, gathered in Brussels on the occasion of the first European Union HCV Policy Summit, on 17 February 2016, are committed to the elimination of hepatitis C in Europe.

- Hepatitis C is a life-threatening disease; it affects millions of people across Europe and has a significant morbidity and premature death burden¹;
- Today, scientific breakthroughs give us the unique opportunity to eliminate hepatitis C in Europe, averting a significant toll in terms of deaths and societal and economic costs;
- The specific challenges of hepatitis C require holistic, people-centred, health system-wide approaches to disease awareness, prevention and integrated care, with all stakeholders combining their diverse skills and resources in a unified response.

We share the vision that eliminating hepatitis C in Europe by 2030 will require us to:



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Co-Chair, Hepatitis B&C Public Policy Association



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Prof. Michael Manns

Co-Chair, Hepatitis B&C Public Policy Association



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Dr. Cristian-Silviu Buşoi

**Member of the European Parliament,
Co-Chair of the Friends of the Liver
MEP Group**



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Dr. Tatjana Reic

President of the European Liver Patients' Association



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Prof. Francesco Negro

**Educational Councillor, European
Association for the Study of Liver**



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Elimination Hepatitis from Europe: The Role of EASL

Francesco Negro, MD

Treasurer elect, EASL Governing Board
Professor of Gastroenterology and Hepatology
University Hospital, Geneva, Switzerland

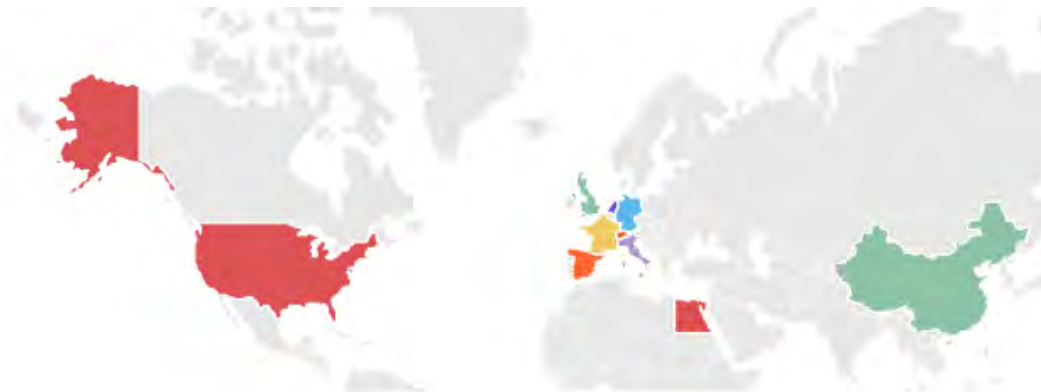
Hepatitis C in Europe

- Epidemiology and continuum of care are fairly characterized
- One third have been diagnosed, but too few have been treated
- Direct-acting antivirals are now available without restrictions in most major Western countries, and prescribed by specialists according to EASL guidelines
- The challenge of migration: ~2.1 million migrants are estimated to be anti-HCV+, with ~30,000 new yearly arrivals

Eliminating viral hepatitis in Eastern Europe: a long and winding road

- Epidemic exploding driven by drug use
- Lack of awareness at all levels (especially political)
- No surveillance systems, no national strategies
- Management guidelines often obsolete
- Limited or no funding for hepatitis programs
- Increasing need in affordable and quality-assured medicines (e.g. public health oriented licensing through MPP)

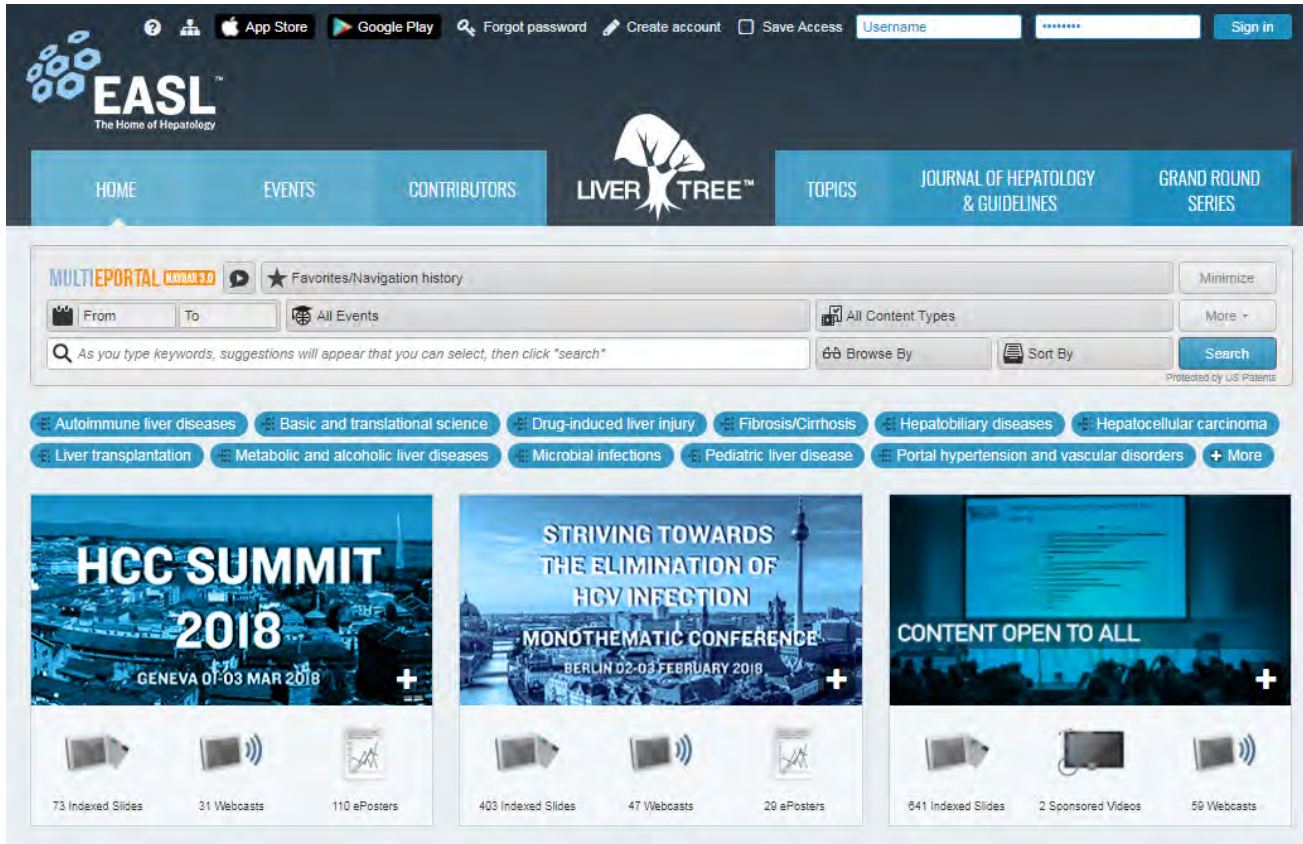
The Role of EASL
To Achieve Hepatitis C Elimination in Europe:
Networking
Education
Research
Policy and Advocacy



Abstracts submitted
2,761
Orals accepted
208
(+11 late breakers)
Posters accepted
1,542
(+32 late breakers)

~10,000 attendees
from 120+ countries

Public health dedicated sessions (EU, EMCDDA, ECDC, WHO, INHSU, MPP...)



The screenshot shows the EASL website interface. At the top, there is a navigation bar with the EASL logo and the tagline 'The Home of Hepatology'. Below this is a secondary navigation bar with links for HOME, EVENTS, CONTRIBUTORS, LIVER TREE™, TOPICS, JOURNAL OF HEPATOLOGY & GUIDELINES, and GRAND ROUND SERIES. A search bar is located on the right side of the top navigation bar, with fields for Username and Password, and a Sign in button. Below the navigation bar is a 'MULTI PORTAL' section with a 'Favorites/Navigation history' button and a 'Minimize' button. A search bar is also present, with a placeholder text: 'As you type keywords, suggestions will appear that you can select, then click "search"'. Below the search bar are several filters for content types, including 'All Content Types', 'Browse By', and 'Sort By'. A 'Search' button is located to the right of these filters. Below the search bar is a row of topic tags: Autoimmune liver diseases, Basic and translational science, Drug-induced liver injury, Fibrosis/Cirrhosis, Hepatobiliary diseases, Hepatocellular carcinoma, Liver transplantation, Metabolic and alcoholic liver diseases, Microbial infections, Pediatric liver disease, Portal hypertension and vascular disorders, and a '+ More' button. Below the topic tags are three featured event cards. The first card is for 'HCC SUMMIT 2018' in Geneva on 03 MAR 2018, with 73 Indexed Slides, 31 Webcasts, and 110 ePosters. The second card is for 'STRIVING TOWARDS THE ELIMINATION OF HCV INFECTION MONOTHEMATIC CONFERENCE' in Berlin on 02-03 FEBRUARY 2018, with 403 Indexed Slides, 47 Webcasts, and 20 ePosters. The third card is for 'CONTENT OPEN TO ALL' with 641 Indexed Slides, 2 Sponsored Videos, and 50 Webcasts. Each card has a '+ More' button and icons for slides, webcasts, and ePosters.

LiverTree™
The official EASL
eLearning portal

EASL Recommendations on Treatment of Hepatitis C 2018[☆]

European Association for the Study of the Liver^{*}

Summary

Hepatitis C virus (HCV) infection is a major cause of chronic liver disease, with approximately 71 million chronically infected individuals worldwide. Clinical care for patients with HCV-related liver disease has advanced considerably thanks to an enhanced understanding of the pathophysiology of the disease, and because of developments in diagnostic procedures and improvements in therapy and prevention. These European Association for the Study of the Liver Recommendations on Treatment of Hepatitis C describe the optimal management of patients with acute and chronic HCV infections in 2018 and onwards.

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Introduction

Hepatitis C virus (HCV) infection is one of the main causes of chronic liver disease worldwide.¹ The long-term natural history of HCV infection is highly variable. The hepatic injury can range from minimal histological changes to extensive fibrosis and cirrhosis with or without hepatocellular carcinoma (HCC). There are approximately 71 million chronically infected individuals worldwide,^{1,2} many of whom are unaware of their infection, with important variations according to the geographical area. Clinical care for patients with HCV-related liver disease has advanced considerably during the last two decades, thanks to an enhanced understanding of the pathophysiology of the disease, and because of developments in diagnostic procedures and improvements in therapy and prevention.

The primary goal of HCV therapy is to cure the infection, i.e. to achieve a sustained virological response (SVR) defined as undetectable HCV RNA 12 weeks (SVR12) or 24 weeks (SVR24) after treatment completion. An SVR corresponds to a cure of the HCV infection, with a very low chance of late relapse. An SVR is generally associated with normalisation of liver enzymes and improvement or disappearance of liver necroinflammation and fibrosis in patients without cirrhosis. Patients with advanced fibrosis (METAVIR score F3) or cirrhosis (F4) remain at risk of life-threatening complications. However, hepatic fibrosis may regress and the risk of complications such as hepatic

failure and portal hypertension is reduced after an SVR. Recent data suggest that the risk of HCC and liver-related mortality is significantly reduced, but not eliminated, in patients with cirrhosis who clear HCV compared to untreated patients and non-sustained virological responders, especially in the presence of cofactors of liver morbidity, such as the metabolic syndrome, harmful alcohol consumption and/or concurrent hepatitis B virus (HBV) infection.³⁻⁹ HCV is also associated with a number of extra-hepatic manifestations and viral elimination induces reversal of most of them with reduction of all-cause mortality.¹⁰

These EASL recommendations are intended as well as a clinical decision management tool. These recommendations are approved by the European Association for the Study of the Liver.

Methodology

These EASL recommendations are based on the expert opinions of the EASL experts who were convened for this purpose. The recommendations are based on the best available evidence and are intended to be used as a guide for clinical practice. The EASL experts were convened for this purpose and the recommendations are based on the best available evidence and are intended to be used as a guide for clinical practice.

Diagnosis

Anti-HCV antibodies are detectable in serum or plasma by enzyme immunoassay (EIA) in the vast majority of patients with HCV infection, but EIA results may be negative in early acute

JOURNAL OF HEPATOLOGY

The Home of Liver Research

Clinical Practice Guidelines

HCV



[☆] Clinical practice guidelines panel: Chair: Jean-Michel Pawlotsky; EASL governing board representative: Francesco Negro; Panel members: Alessio Aglietta, Marina Berenguer, Olav Dalgard, Geoffrey Dusheiko, Fiona Marra, Massimo Puoti, Heiner Wedemeyer.

^{*} Corresponding author: Address: European Association for the Study of the Liver (EASL), The EASL Building – Home of Hepatology, 7 rue Dublin, CH 1203 Geneva, Switzerland. Tel.: +41 (0) 22 807 03 60; fax: +41 (0) 22 328 07 24. E-mail address: easloffice@easloffice.eu.





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EASL HCV ADVISOR



Fostering evidence-based policy

HEPAHEALTH project on incidence, prevalence, mortality (UK Health Forum):

- Top line results presented at the 2018 International Liver Congress
- Manuscript in press in the Journal of Hepatology

Collaboration with the ECDC:

- MoU to work on joint projects and supply scientific advice
- Project on the viral hepatitis attributable fraction of cirrhosis, HCC and liver-related mortality (Lisbon, Oslo, Sofia)

Member of the **EU Commission Civil Society Forum on HIV, TB and Hepatitis**

EASL Policy Statement: *Hepatitis C Elimination*

Cooperation between patients and hepatologists in the European region

- EASL works closely with ELPA on hepatitis (and other topics) advocacy at EU level to call for an EU strategy in viral hepatitis
- EASL attends ELPA policy and strategic planning meetings annually
- *Friends of the Liver* (group of members of the European Parliament)



Breaking Down National Goals Into Smaller Goals for Individual Population Segments

Editorial



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HEPATOLOGY

Micro-elimination – A path to global elimination of hepatitis C

Jeffrey V. Lazarus^{1,2,*}, Stefan Wiktor³, Massimo Colombo⁴, Mark Thursz⁵,
on behalf of the EASL International Liver Foundation

¹Barcelona Institute for Global Health (ISGlobal), Hospital Clínic, University of Barcelona, Barcelona, Spain; ²CHIP, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark; ³Department of Global Health, University of Washington, USA; ⁴Clinical and Research Center Humanitas, Rozzano, Italy; ⁵Division of Digestive Diseases, St Mary's Hospital, Imperial College London, London, UK

Eberhard Schatz

**Coordinator, CORRELATION Network &
European Civil Society Forum**



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Session 1: Burden of disease and pathways of elimination

Chairs:

Prof. Georgios Papatheodoridis, National and Kapodistrian University of Athens

Prof. Mojca Maticic, University Medical Centre Ljubljana



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Burden of disease and pathways of elimination

Prof. Mojca Maticic, MD, PhD

University Medical Centre Ljubljana
Faculty of Medicine, University of Ljubljana
Slovenia

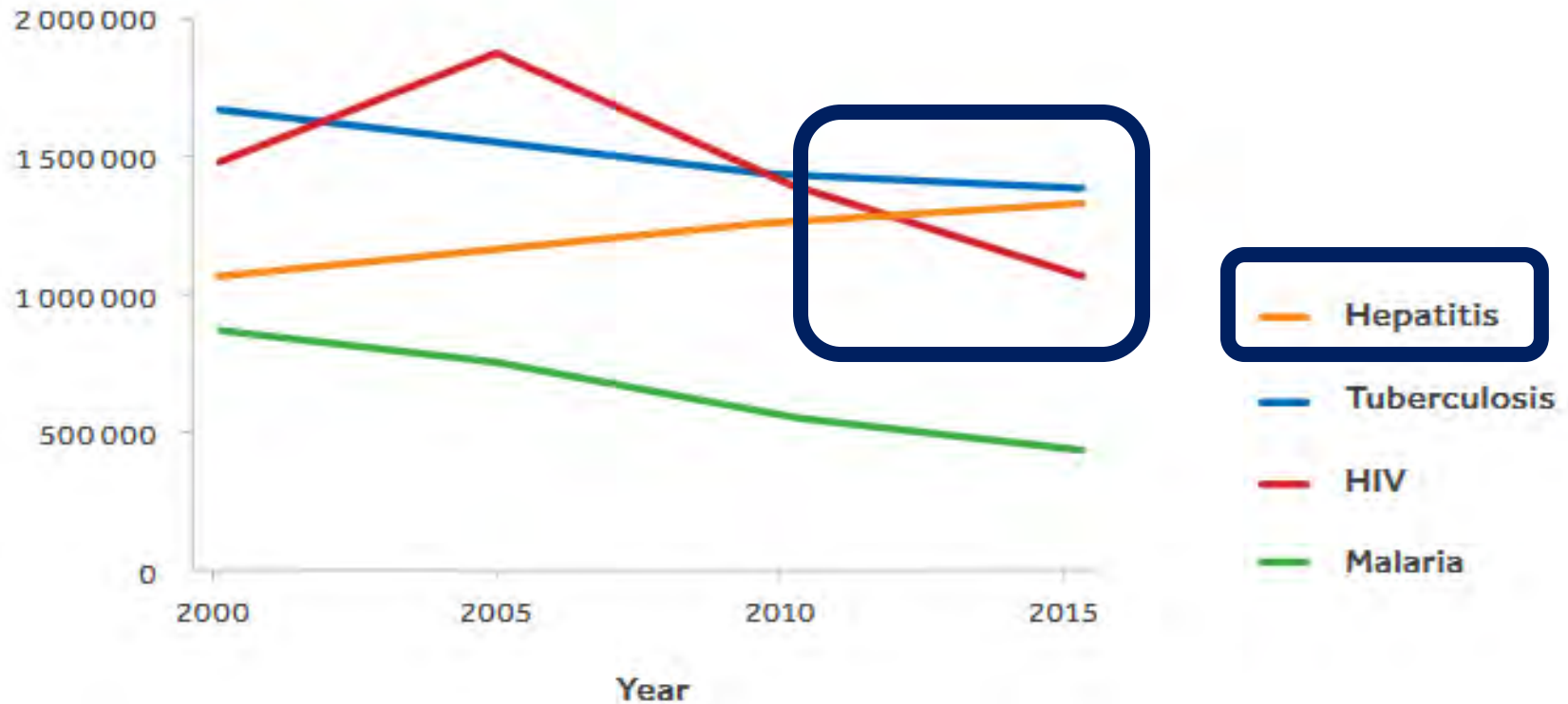
Brussels: June 6, 2018

Hepatitis C remains a global health problem



Though curable,
HCV continues to have a large
human, social and economic impact

Global number of deaths due to infectious diseases, period 2000-2015



By the year 2030:
20 million new deaths will occur
if **NO ACTION** is going to be undertaken

The **impact of inaction** in HCV:

Global number of deaths continues to rise

>400,000 people die each year
from HCV-related liver diseases even though
HCV is curable

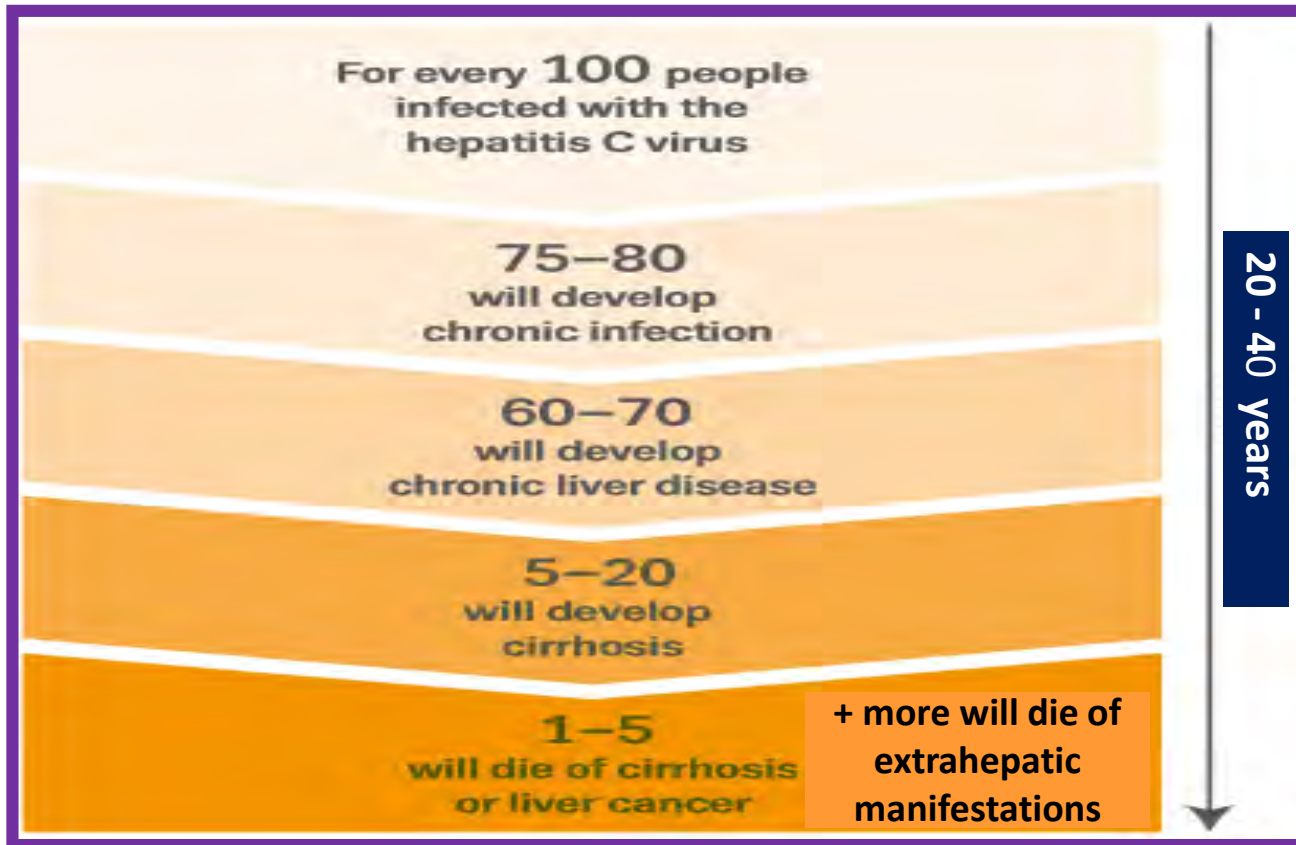
**>45 deaths
every hour**



**>1,095 deaths
every day**

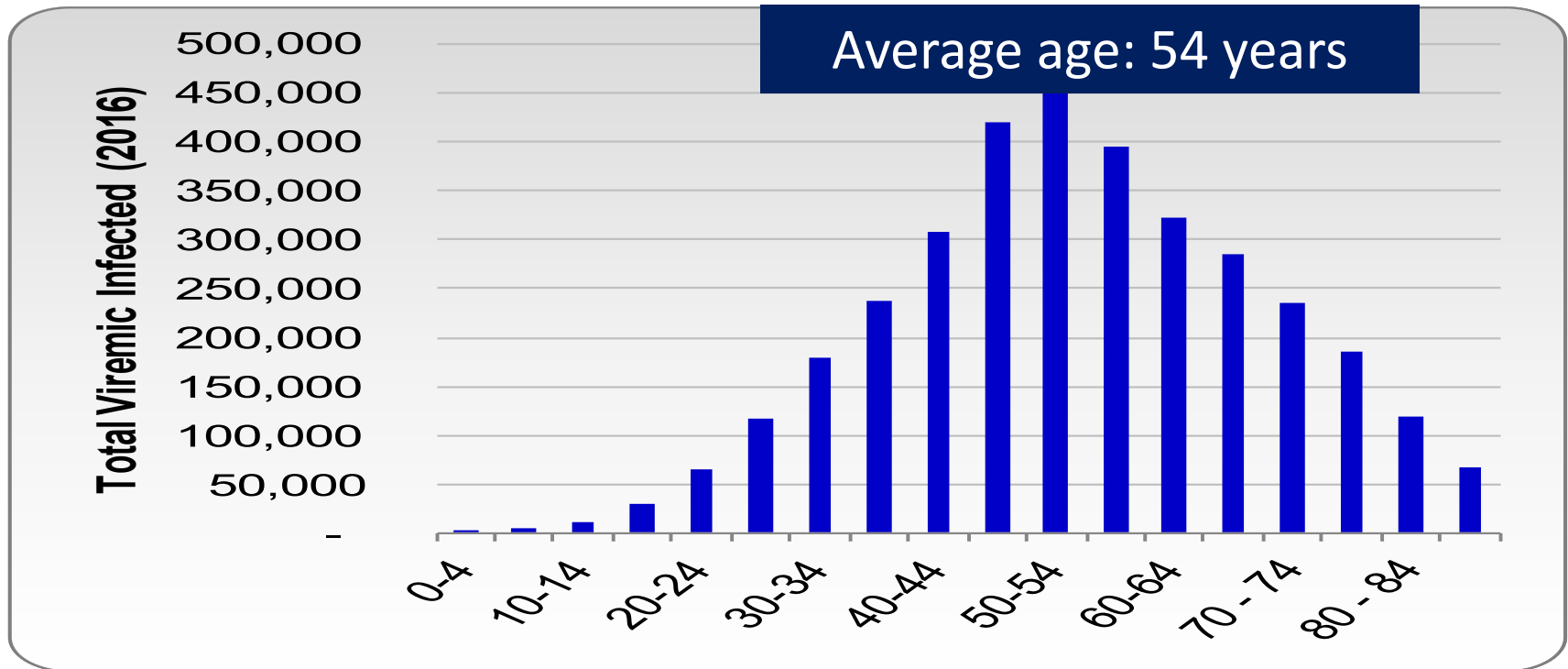
WHY ??

The course of HCV infection with no treatment:



It takes >20 years of infection to develop life-threatening conditions

Age distribution of HCV-infected persons in EU in 2015



The population of HCV-infected **has been ageing** – reaching **a critical period** to develop life-threatening conditions

Here is the problem

71 million

The number **chronically infected**

80%

The proportion of **UN-diagnosed**

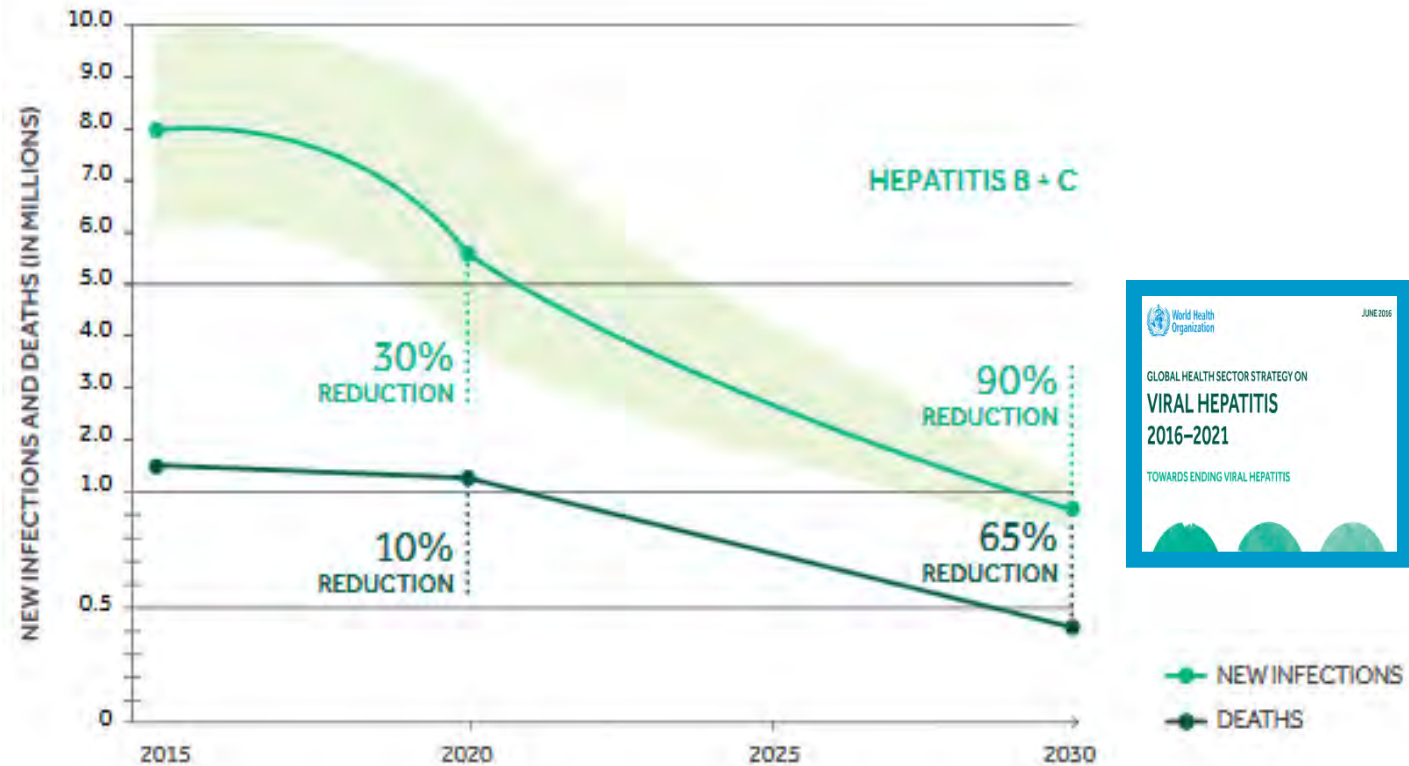
93%

The proportion of **UN-treated**

Here is the solution:

WHO strategy

towards elimination of viral hepatitis as a public health threat

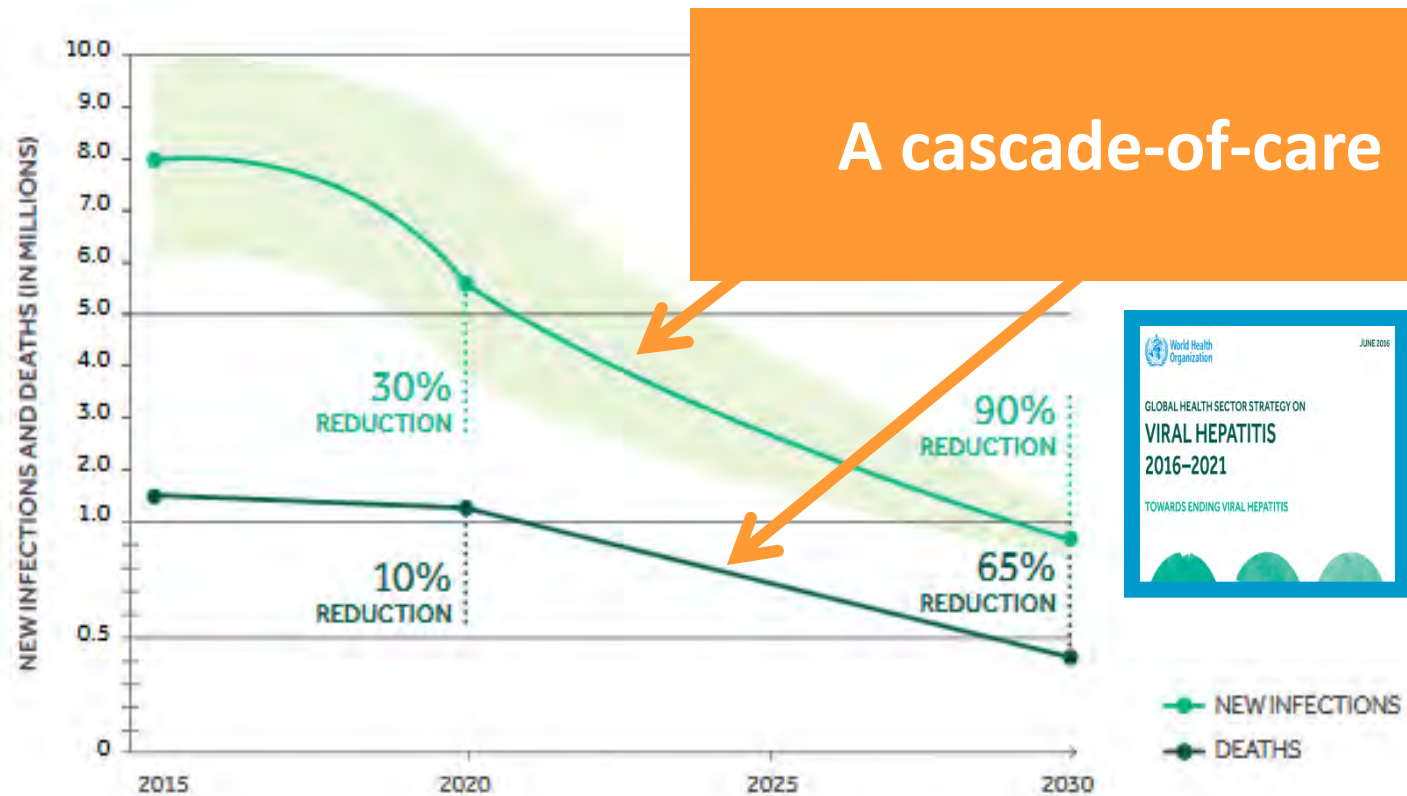


Targets for reducing new cases of infection and deaths from chronic hepatitis C

Here is the solution:

WHO strategy

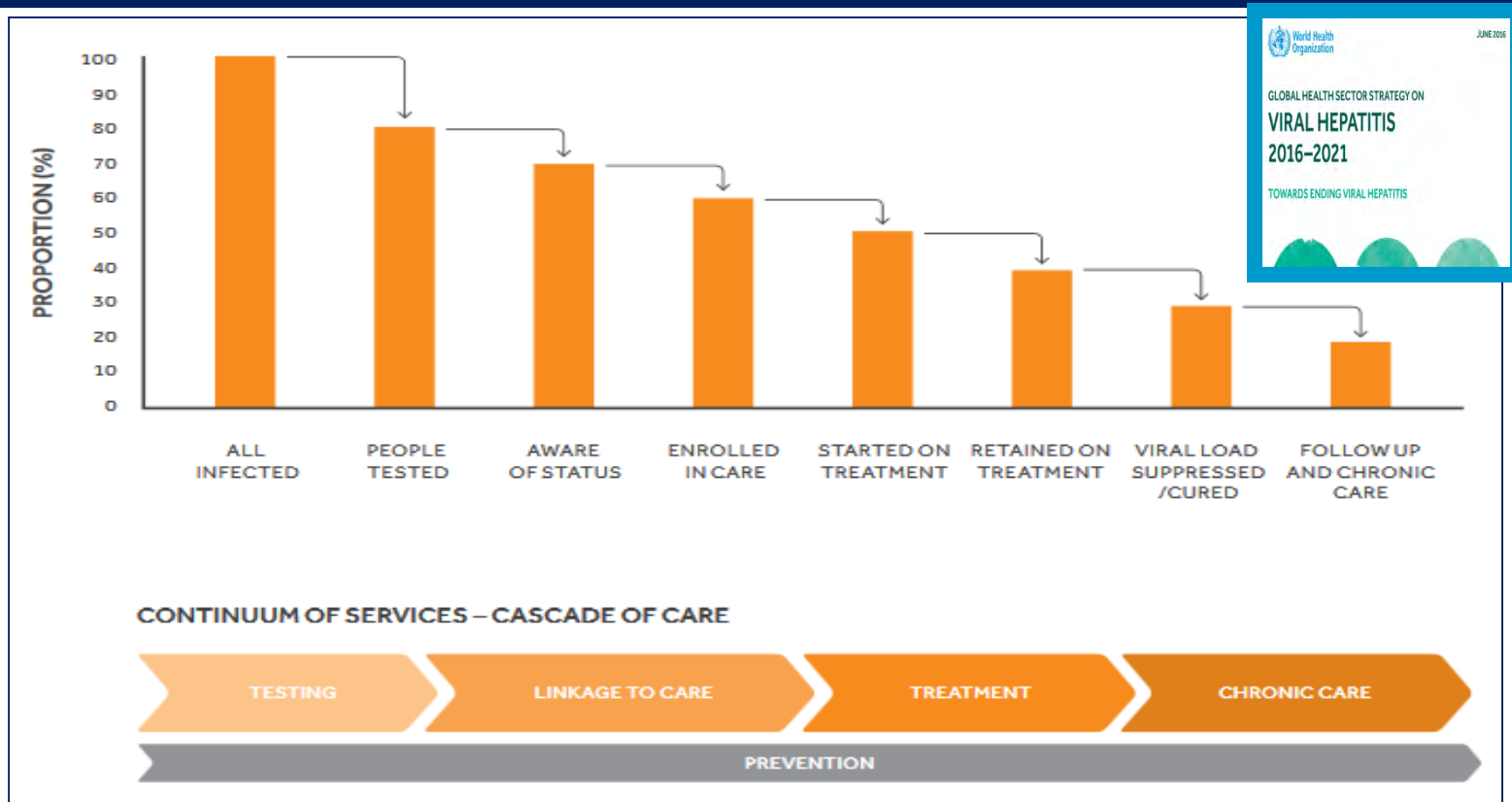
towards elimination of viral hepatitis as a public health threat



Targets for reducing new cases of infection and deaths from chronic hepatitis C

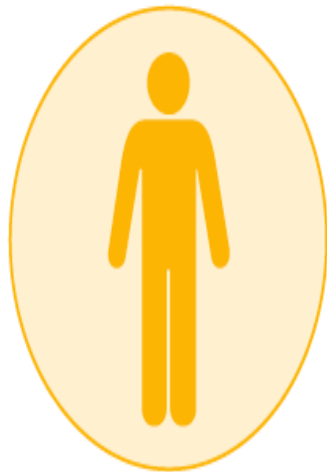
Here is the solution:

The continuum of services for HCV management



**Several barriers and gaps
in a cascade-of-care**

Barriers and gaps in a cascade-of-care



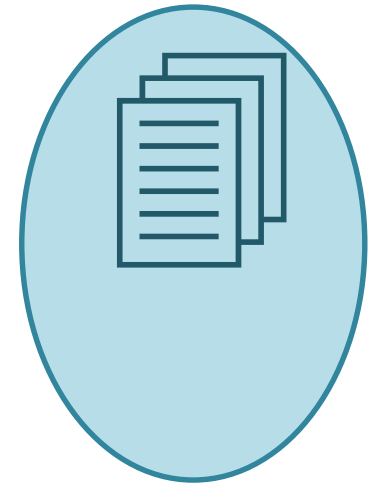
PATIENT



PRACTITION



SYSTEM



POLICY

Barriers and gaps need to be **adressed**
and **solutions** need to be found
and subsequently **funded**

WHO recommendations to the member states

National strategy

National action plan

National clinical guidelines

Availability and access to a cascade-of-care

...need to be set up
to achieve WHO goals towards HCV elimination

Simplification of existing models of care



This is all that we need !!!

Session 1:

Burden of disease and pathways of elimination:

Objective:

- To identify **routes** guiding to the elimination of hepatitis C
- To identify the **challenges** that it is facing at different levels

Dr. Homie Razavi

**Managing Director, The Centre for
Disease Analysis Foundation**



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HCV Elimination in European Union: Burden, Pathways, and Cost

H. Razavi, PhD, MBA

June 6, 2018



Conflict of Interest Statement

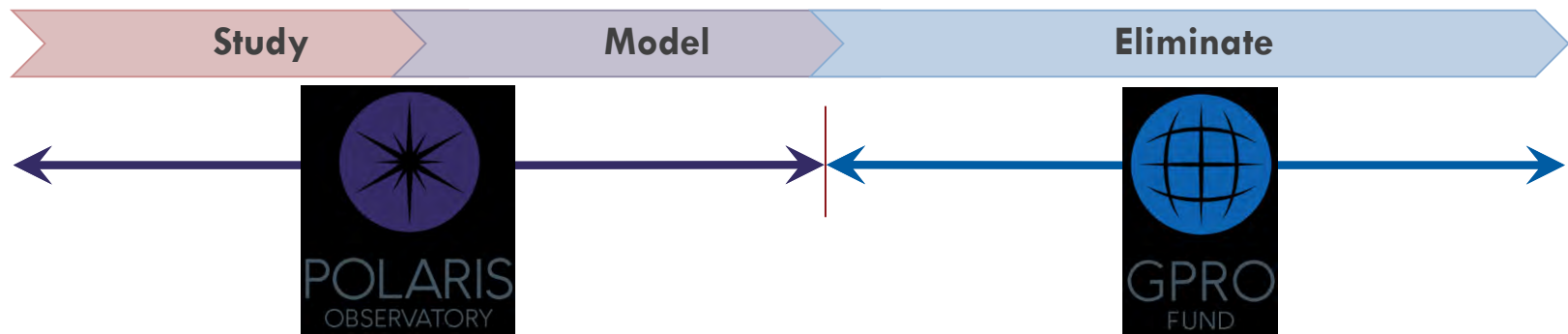
- H. Razavi has not received any remuneration from pharmaceutical companies.
- He is the managing director of Center for Disease Analysis (CDA).
- He has been a member of advisory boards for Gilead and AbbVie. All proceeds went to CDA Foundation.
- CDA Foundation has received grants from CDC Foundation, John Martin Foundation, The Association of State and Territorial Health Officials (ASTHO), Zeshan Foundation, Vaccine Impact Modeling Consortium, WHO WPRO, WHO Geneva, Swiss Federal Office of Public Health, Brazil MoH, Center for Disease Analysis, and private donors.
- CDA has received research funding from Gilead Sciences, AbbVie, & Intercept Pharma.

CDA Foundation is a public non-profit. Please donate & support our work.

CDAF is a non-profit organization with the goal of assisting countries in achieving the 2030 hepatitis elimination targets



We work to **study, model & eliminate** hepatitis. We accomplish this through our two major initiatives:

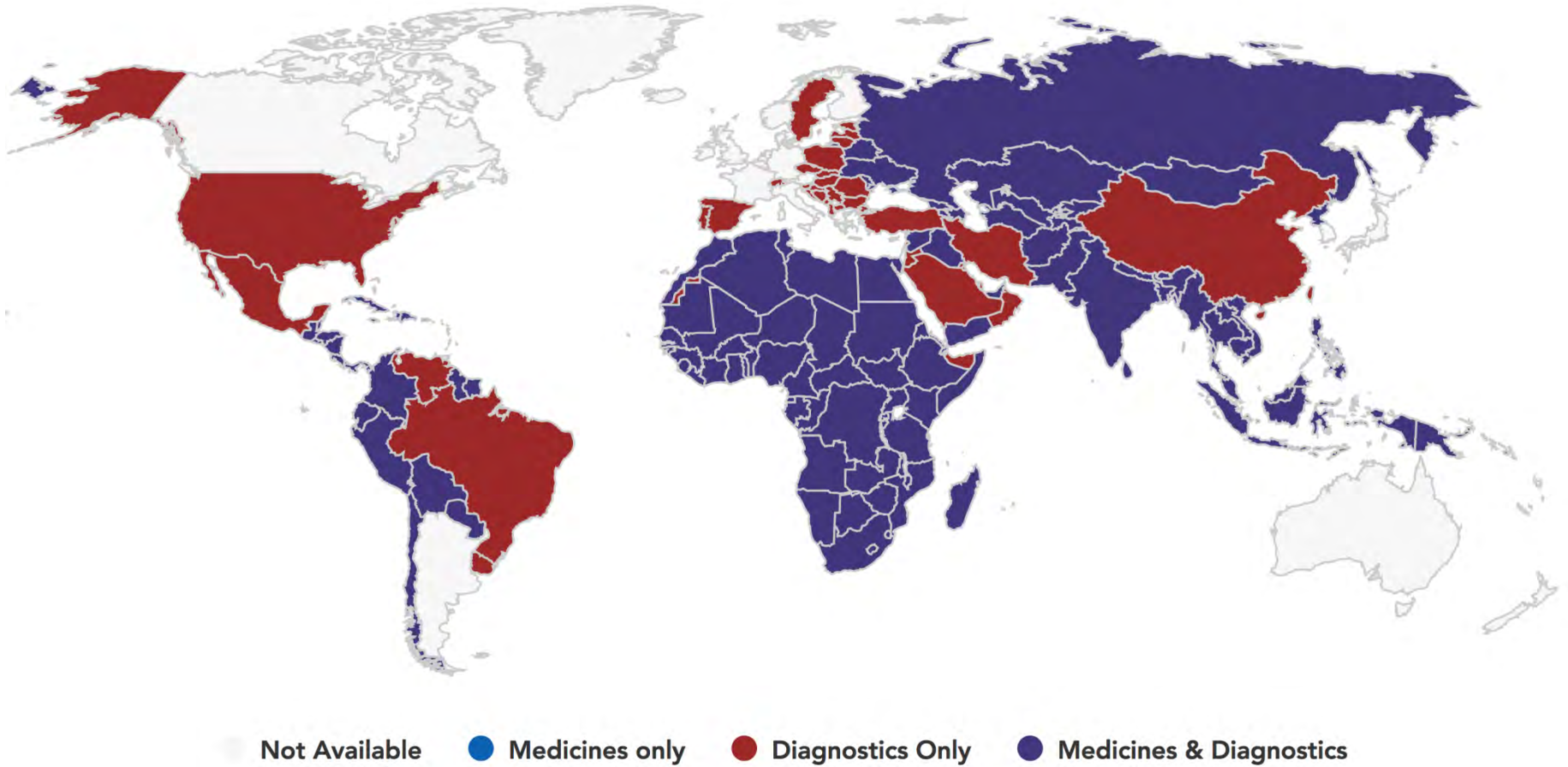


Provide collaborators with epidemiological data, modeling tools, training and decision analytics to support eliminating Hepatitis B and C globally by 2030.

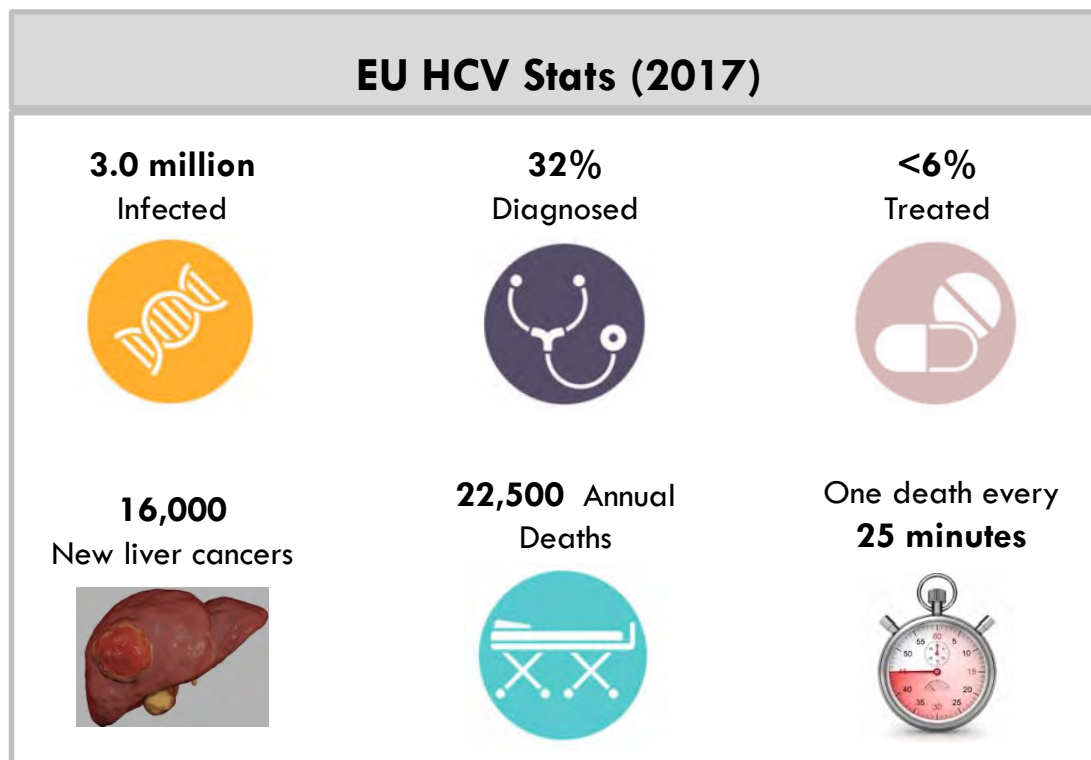
Improve access to medicines and diagnostics, and develop scalable, sustainable funding mechanisms for low and middle-income (LMIC) countries. Provide optimized hepatitis elimination programs.



Countries covered by the Global Procurement (GPRO) Fund



Despite the availability of a cure, every 25 minutes, an HCV infected person died of liver complications in the European Union in 2017

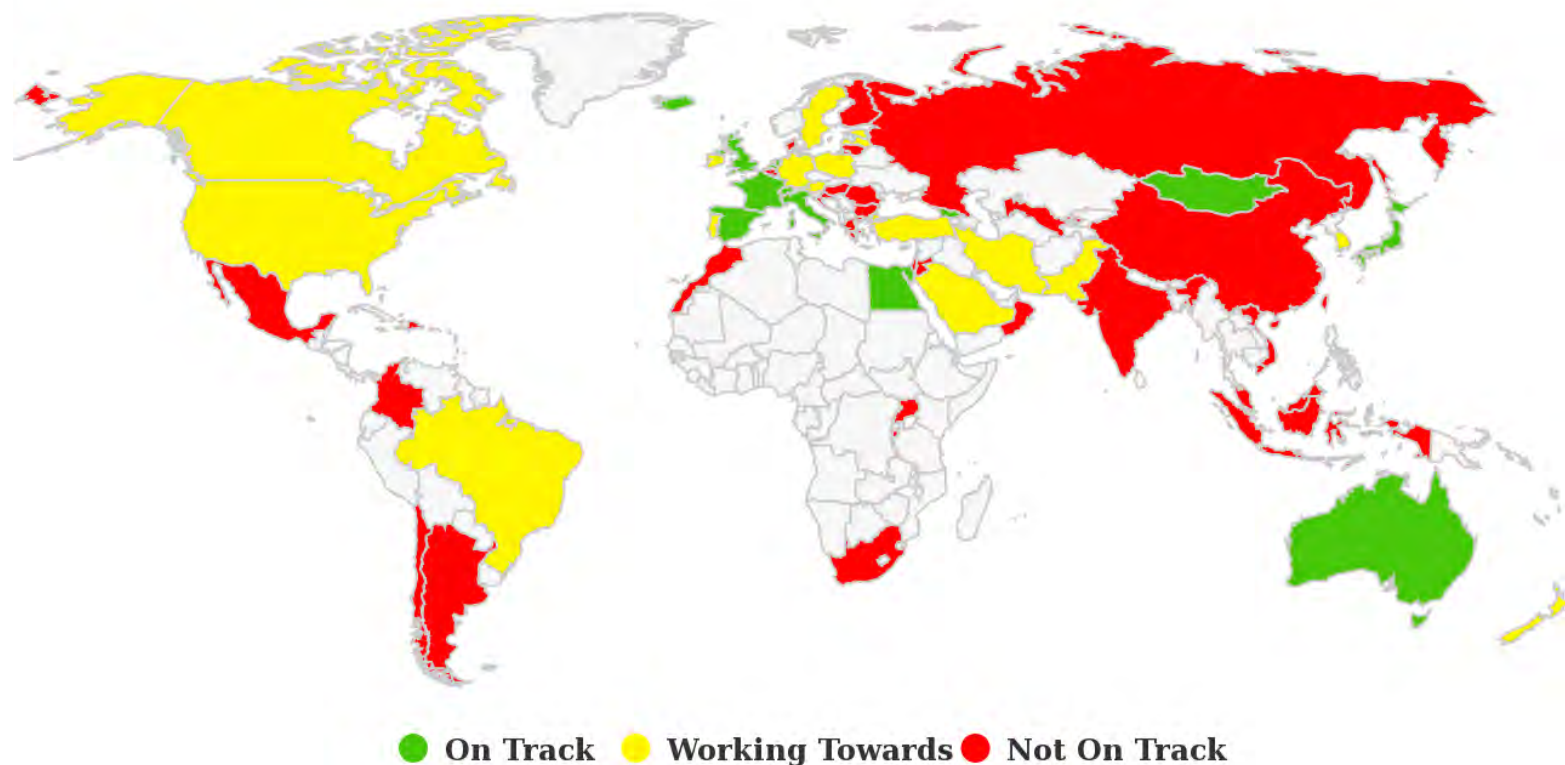


2/3 of the HCV infections in the EU remain undiagnosed.

Of the 12 countries on path to elimination in 2017, five are in the European Union

HCV Elimination Targets

2017



Australia
Egypt
France

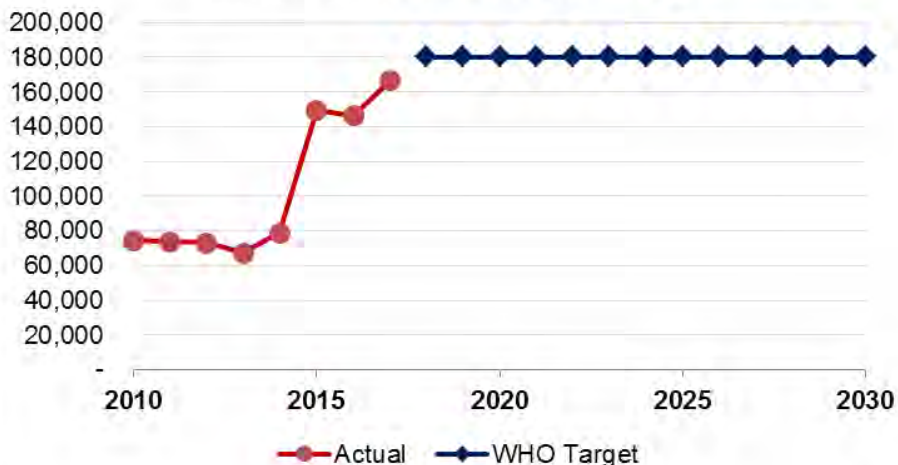
Georgia
Iceland
Italy

Japan
Mongolia
Netherlands

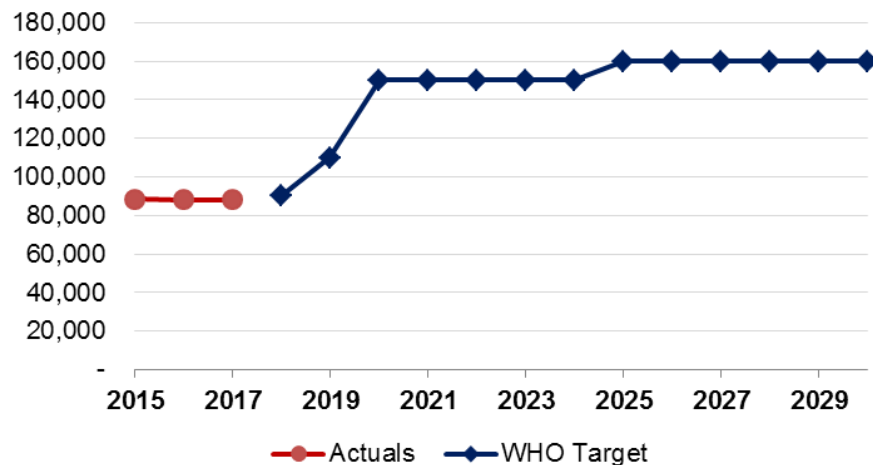
Spain
Switzerland
UK

The EU only needs to diagnose 160,000 & treat 180,000 annually to reach the 2030 WHO elimination targets

HCV Treated Patients in EU

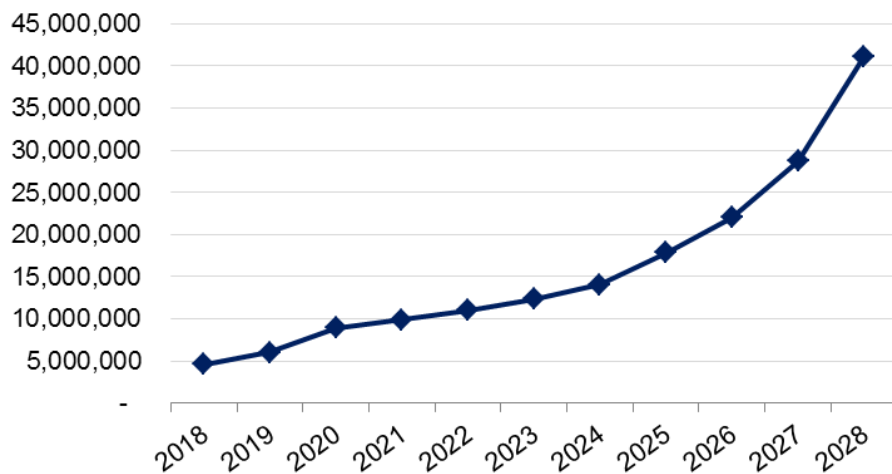


Newly Diagnosed HCV Cases in EU

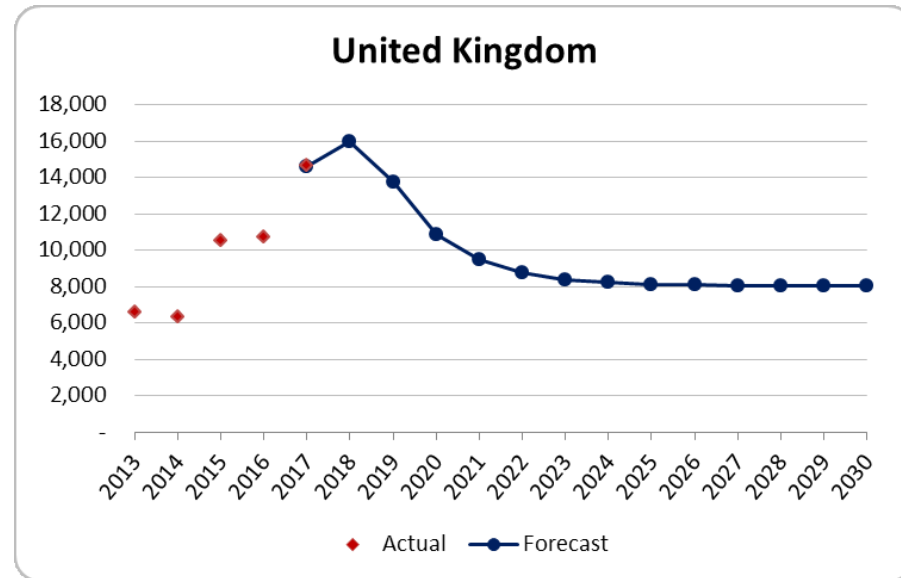
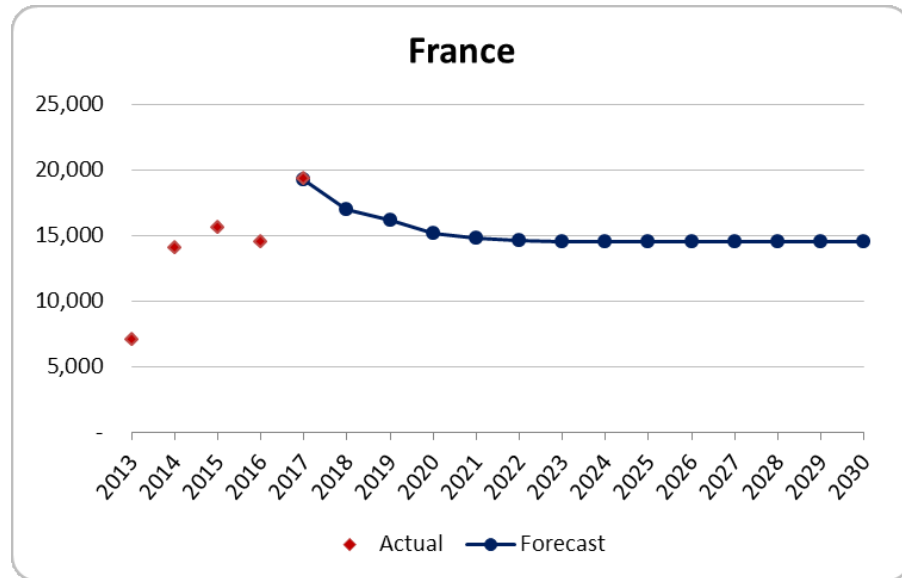
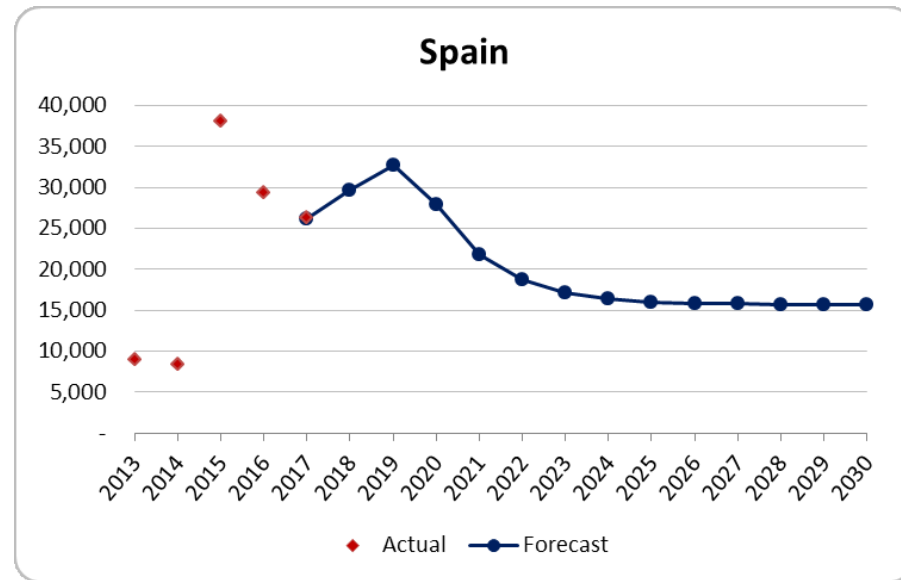
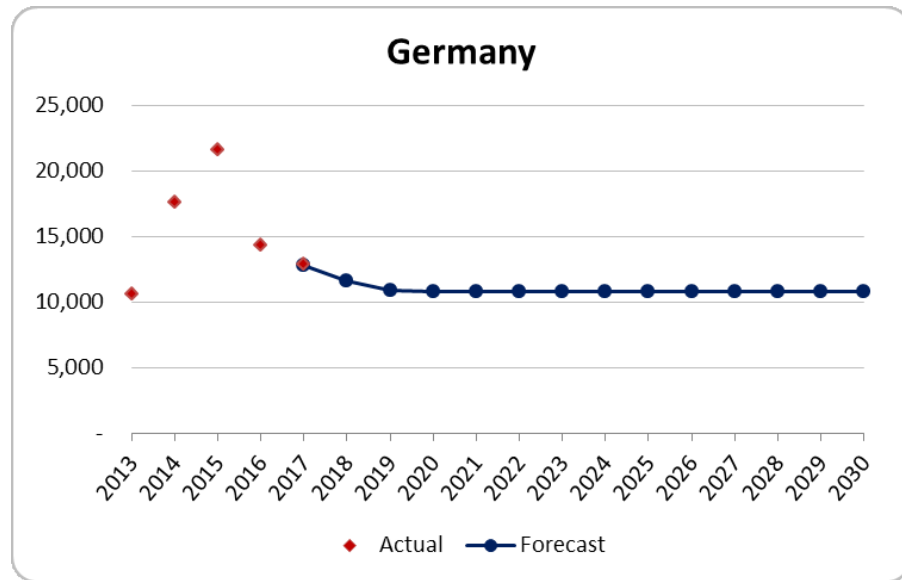


The number of people that need to be screened (each year) will have to increase to find the remaining undiagnosed individuals

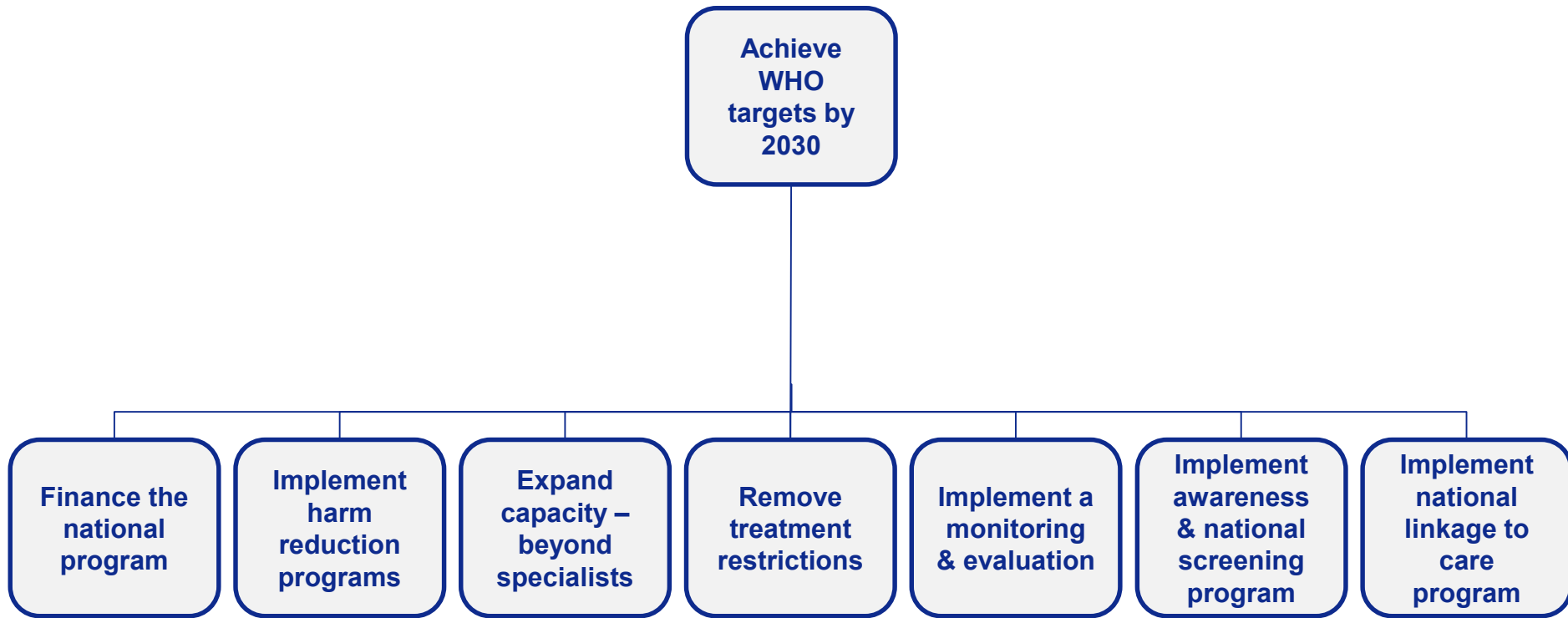
Number Needed to be Screened



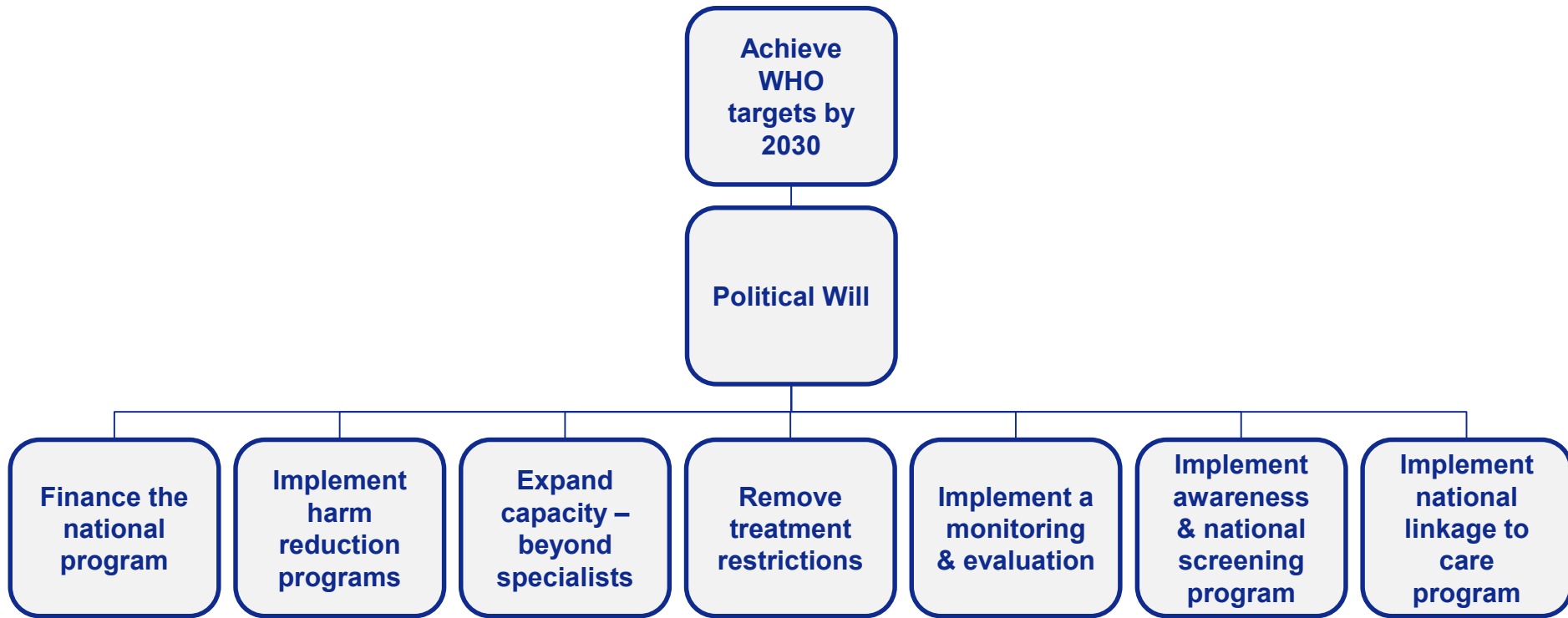
Unfortunately, history tells us that it is very difficult to continue to treat the same number of patients



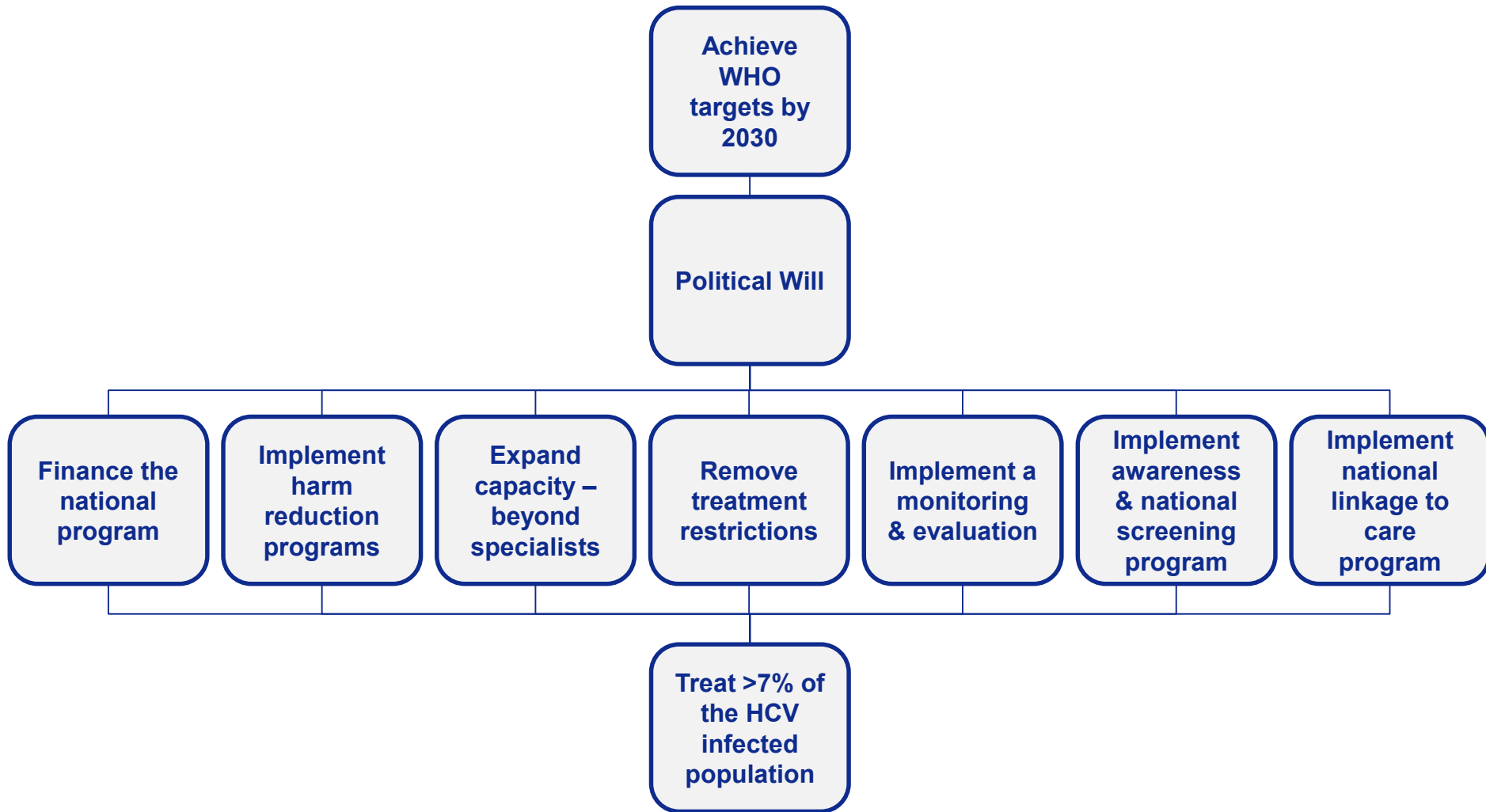
The seven requirements to achieve the 2030 elimination targets



Political will is the only reliable predictor of a country achieving the WHO 2030 elimination targets



The most reliable measure of progress is treatment rate



Conclusions:

- Hepatitis C represents a major burden in the European Union
- The cost of inaction is large – 136,000 additional deaths, 90,000 additional HCC cases, and 71,000 decompensated cirrhosis cases (between 2017-2030)
- EU countries with a high treatment rate will not be able to sustain the treatment without screening
- Political-will is the biggest predictor of whether a country will achieve the 2030 elimination targets

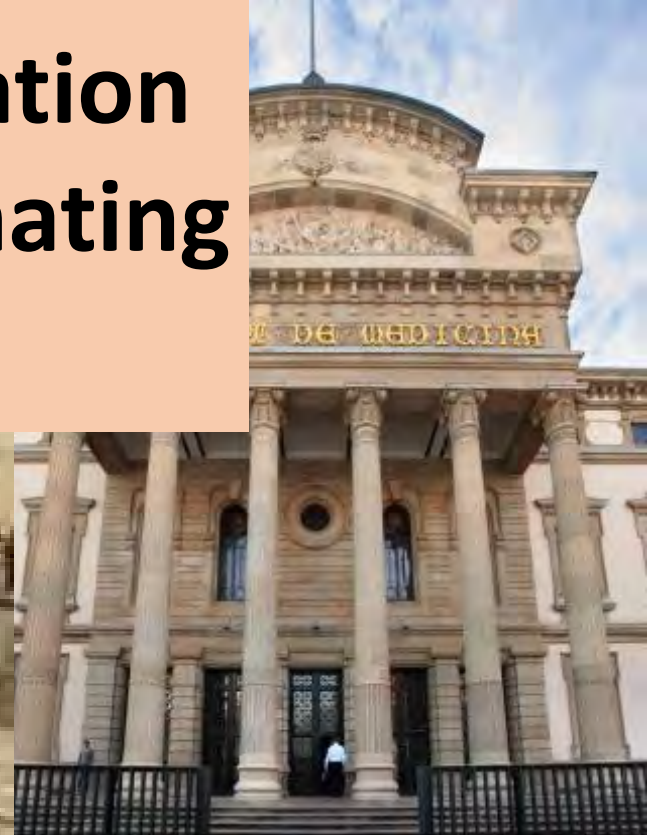
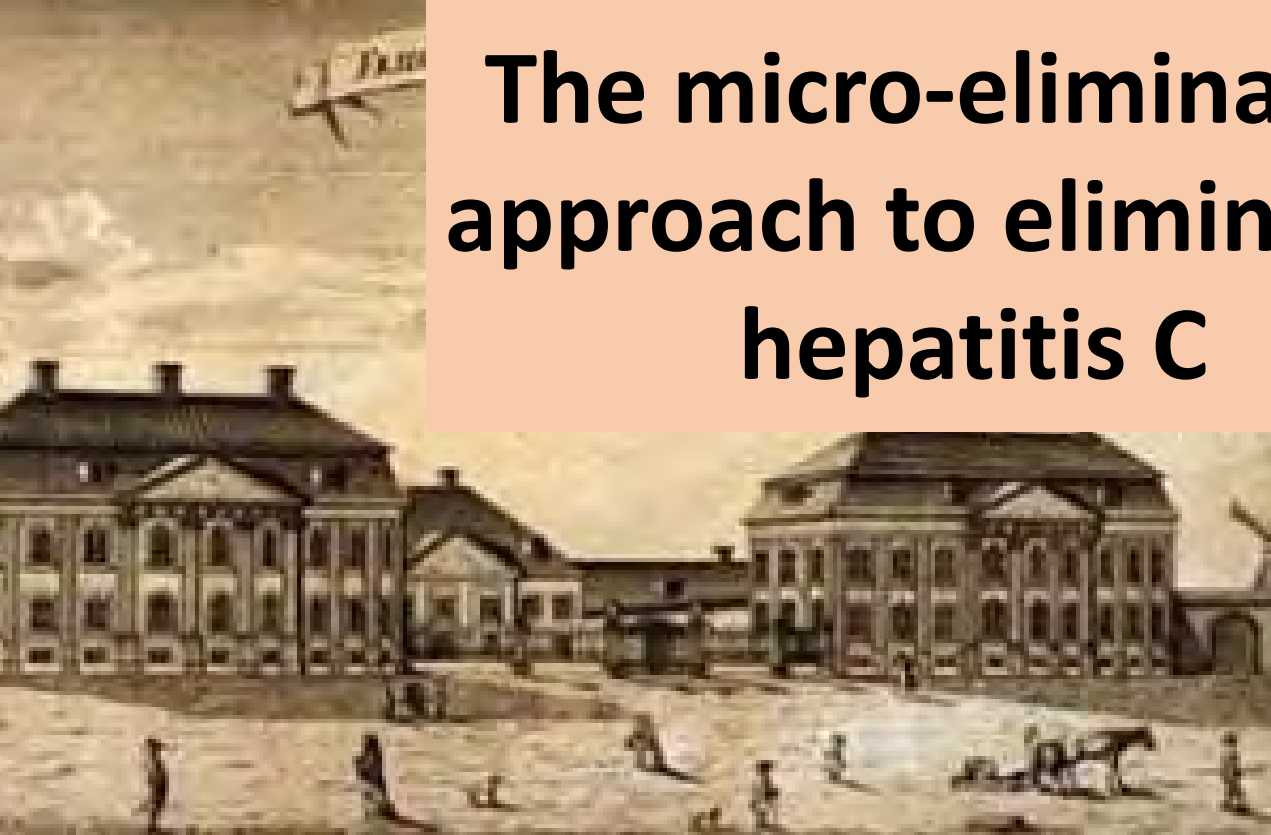
Prof. Jeffrey Lazarus

**Associate Professor, University of
Barcelona, ISGlobal**



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The micro-elimination approach to eliminating hepatitis C



Prof Jeffrey V. Lazarus [Jeffrey.Lazarus@ISGlobal.org]

Associate Researcher, ISGlobal, Hospital Clínic - University of Barcelona
Associate Professor, Faculty of Medicine, University of Barcelona
Affiliated Professor, CHIP, Rigshospitalet, University of Copenhagen,
WHO Collaborating Centre on HIV and Viral Hepatitis



Disclosures

- Grants and personal fees from AbbVie, CEPHEID, Gilead Sciences, MSD
- Research grants from non-governmental organisations including the European Liver Patients Association and the World Hepatitis Alliance
- Previously employed by international agencies: Global Fund, World Health Organization

A couple of questions...

1. Do you believe that the elimination of HCV as a major public health threat by 2025 is possible?
2. In which populations do you feel HCV elimination is *most* feasible in now?



WHO Global Health Sector Strategy on Viral Hepatitis 2016–2021



28 May 2016: The first of its kind, WHO publishes a global strategy aiming for elimination of viral hepatitis as a public health threat by 2030

Source: WHO Global Health Sector Strategy on viral hepatitis. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf?ua=1 (Accessed August 2016)

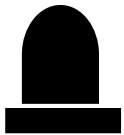
Global Health Sector Strategy

HCV targets at a glance



Incidence targets

- **30%** reduction in new HCV infections by 2020
- **80%** reduction in new HCV infections by 2030



Mortality targets

- **10%** reduction in mortality by 2020
- **65%** reduction in mortality by 2030



Harm reduction

- Increase in sterile needle and syringes provided per PWID/year from **20** in 2015 to:
 - **200** by 2020
 - **300** by 2030



Testing targets

- **90%** of people aware of HCV infection by 2030

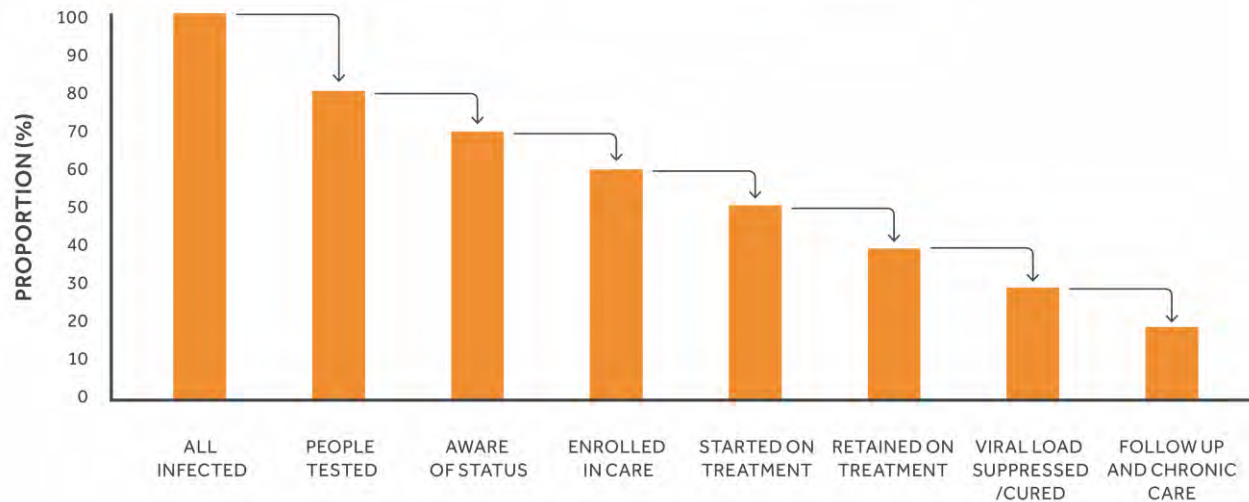


Treatment targets

- **80%** of people treated by 2030

Source: WHO GHSS. http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf?ua=1 (Accessed August 2016).

The continuum of viral hepatitis services and the retention cascade



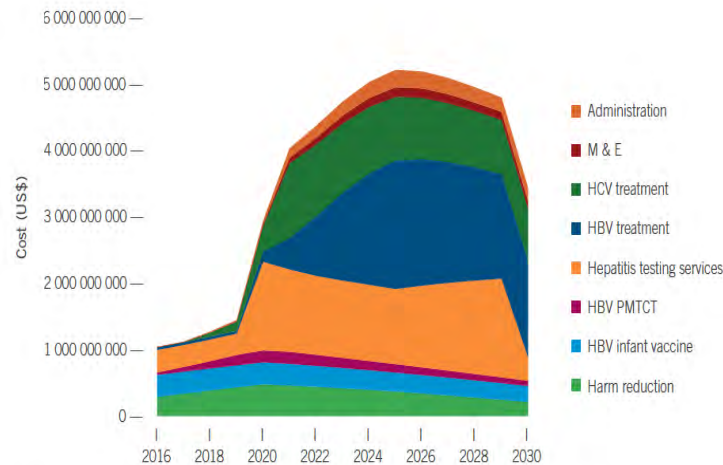
CONTINUUM OF SERVICES – CASCADE OF CARE



Source: WHO Global Hepatitis Report, 2017. Available at www.who.int/hepatitis/publications/global-hepatitis-report2017/en/ (accessed May 2017).

Elimination is Daunting for the Health System

Cost of implementing the WHO global health sector strategy on viral hepatitis, 2016–2030



HBV: hepatitis B virus; HCV: hepatitis C virus; M&E: monitoring and evaluation; PMTCT: prevention of mother-to-child transmission.



Challenging

Costly

Complex

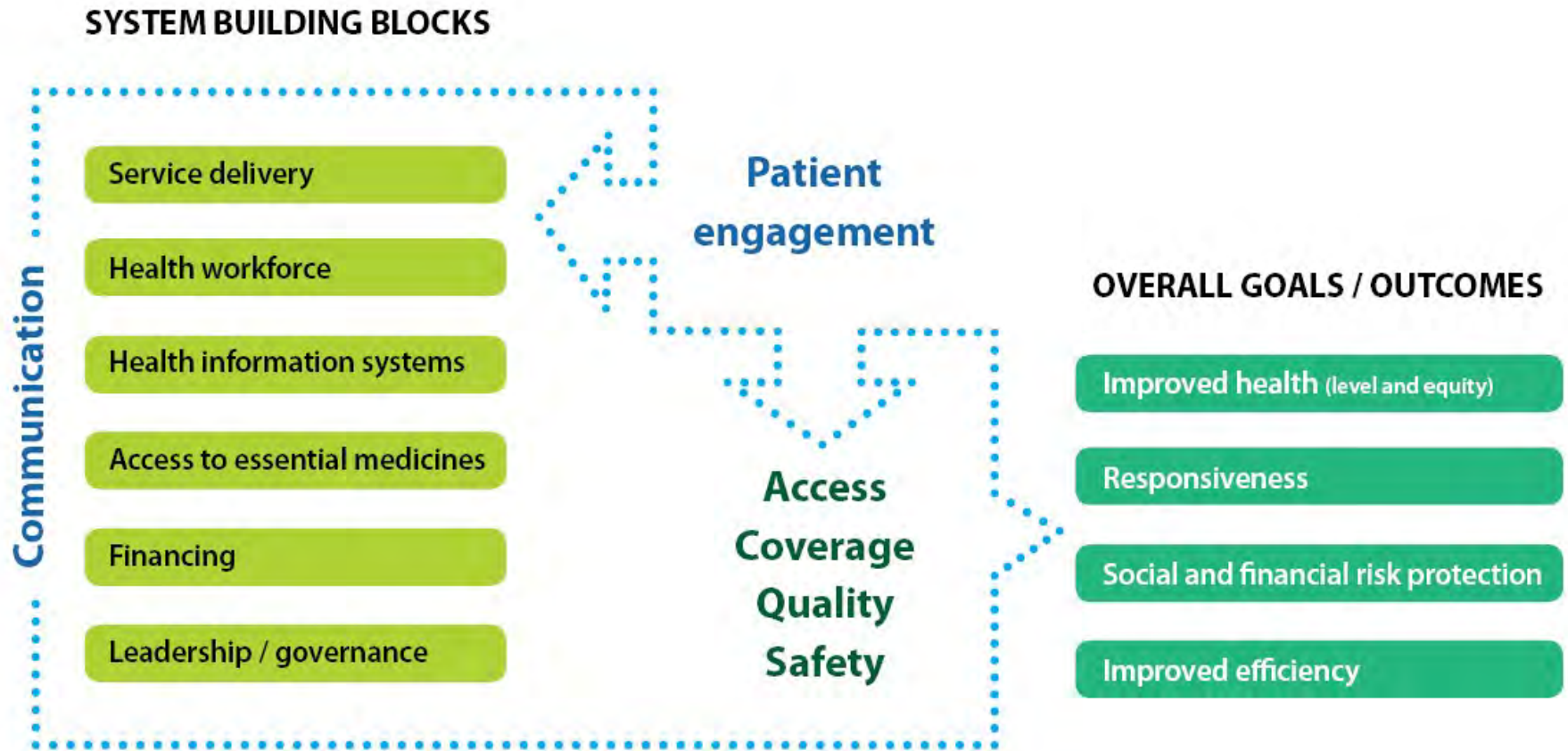
Sources: Lazarus JV *et al.* The micro-elimination approach to eliminating hepatitis C: strategic and operational considerations. *Seminars in Liver Disease*, In press July 2018.

Lazarus JV, Wiktor SZ, Colombo M, Thursz M. Micro-elimination – a path to global elimination of hepatitis C. *Journal of Hepatology*, July 2017.



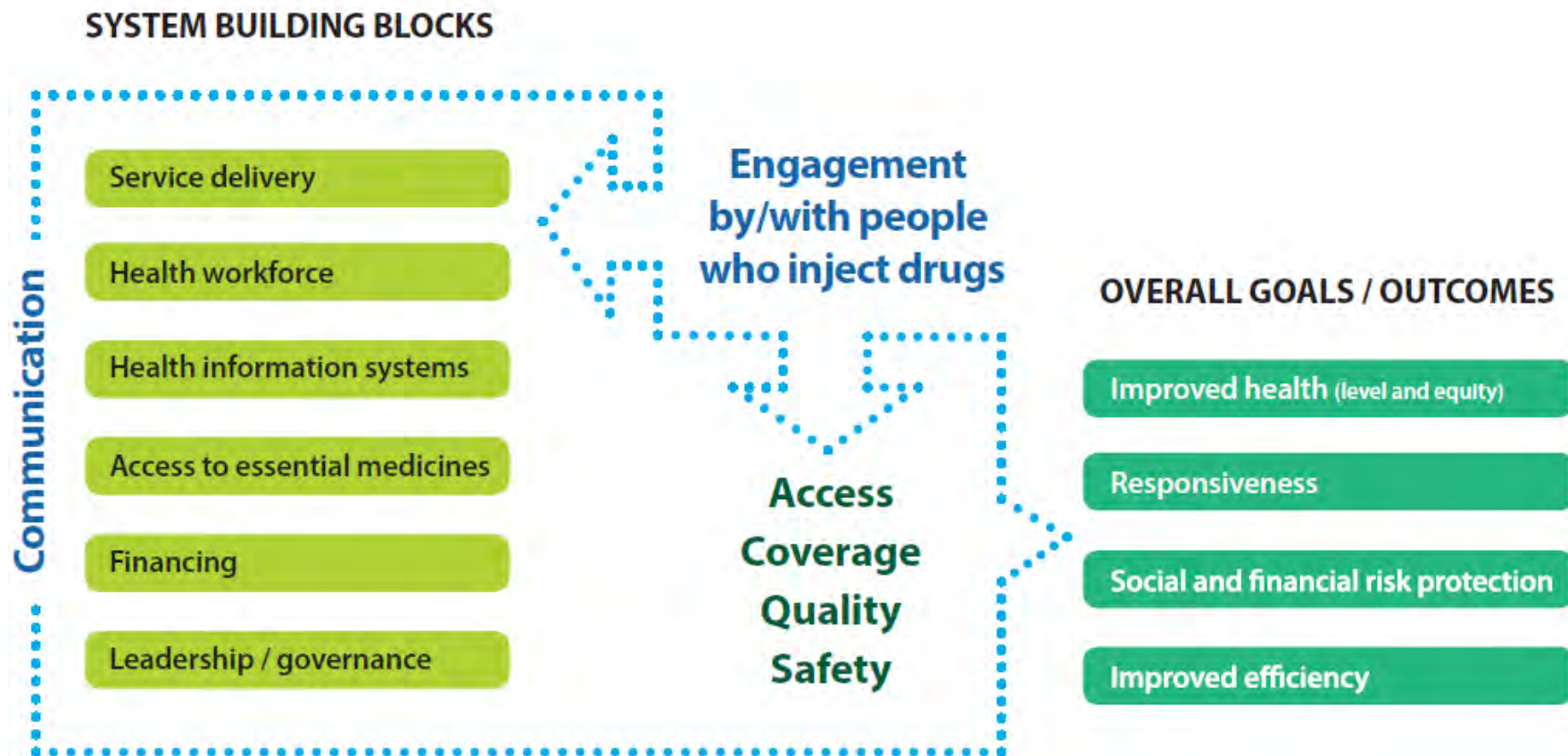
@JVLazarus

A paradigm change: The central role of people and communication



Source: Lazarus and France. A new era for the WHO health system building blocks? 2014.
Adapted from WHO 2007.

Engagement includes people who inject drugs (PWID)

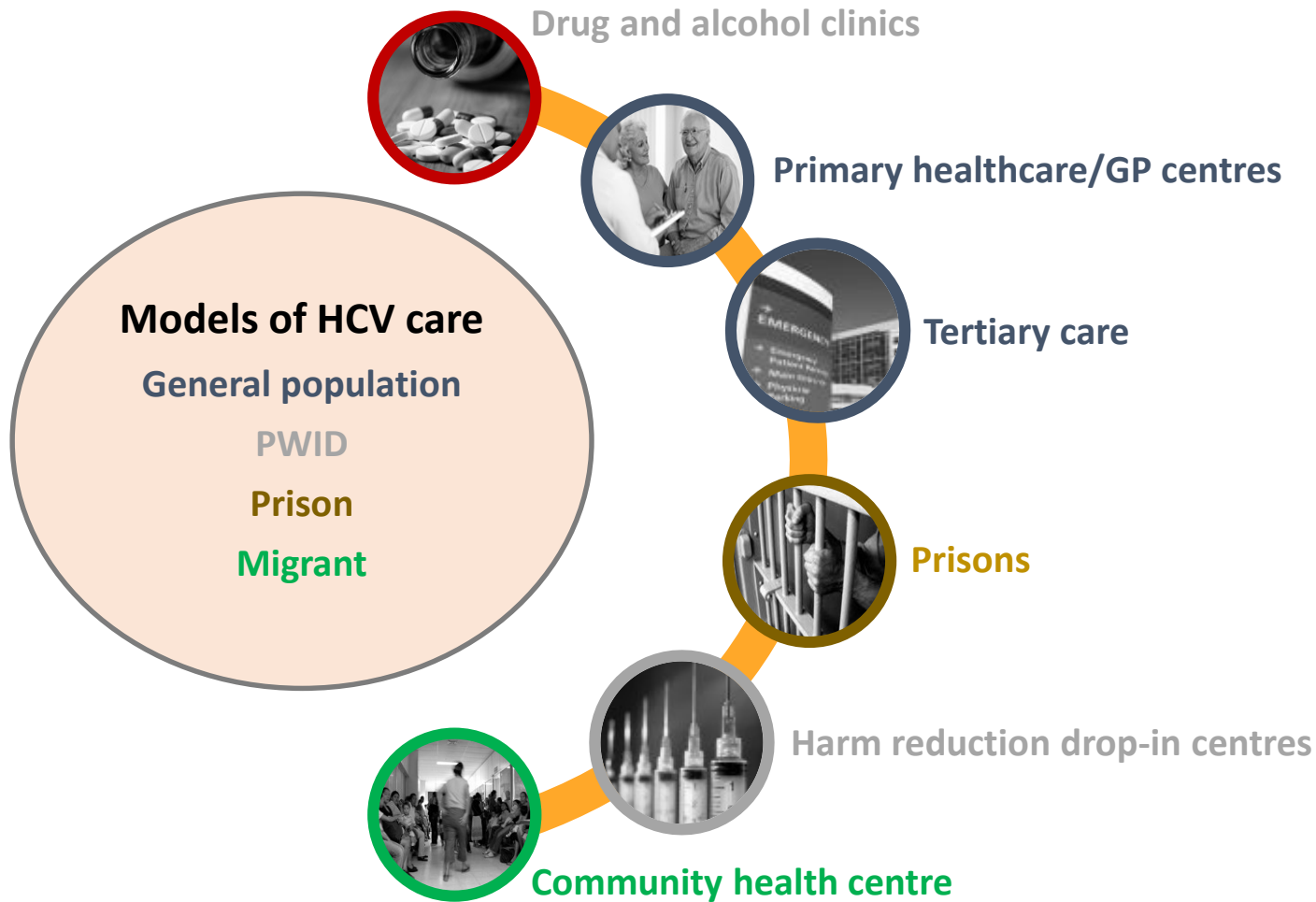


Source: Day *et al* on behalf of the International Network on Hepatitis in Substance Users (INHSU). Elimination of HCV as a major public health concern among people who inject drugs by 2030: What are the remaining key challenges and recommendations for action from a health systems perspective? *Liver Int.* In press 2018.

@JVLazarus

Different models of HCV care are needed for different HCV subpopulations

Multiple models essential



Micro-elimination approach

Generally speaking, micro-elimination approaches should meet *the following criteria*, although these criteria may need to be adapted to different epidemiologic situations and geographic settings:

- There is a plan for how to tailor health resources and services to overcome known barriers and achieve high levels of HCV diagnosis and treatment in one or more clearly definable populations of interest within a specified timeframe.
- The plan sets forth achievable annual targets, basing these on mathematical modeling when relevant to determine the levels of diagnosis and treatment required to progress to the plan's ultimate elimination targets.
- The plan is developed and implemented through a multi-stakeholder process, with essential participants including government officials, health service providers, and civil society representatives.
- Progress and outcomes are monitored and publicly reported using indicators selected at the outset of the process.

Sources: Lazarus JV *et al.* The micro-elimination approach to eliminating hepatitis C: strategic and operational considerations. *Seminars in Liver Disease*, In press July 2018.

HCV (micro-) elimination in certain populations is feasible in the short-to-medium term



**Decompensated
cirrhotics**



**Veterans/Military
personnel**



**Patients with
haemophilia**



**Transplant
patients**



HIV/HCV co-infected



PWID, prisoners

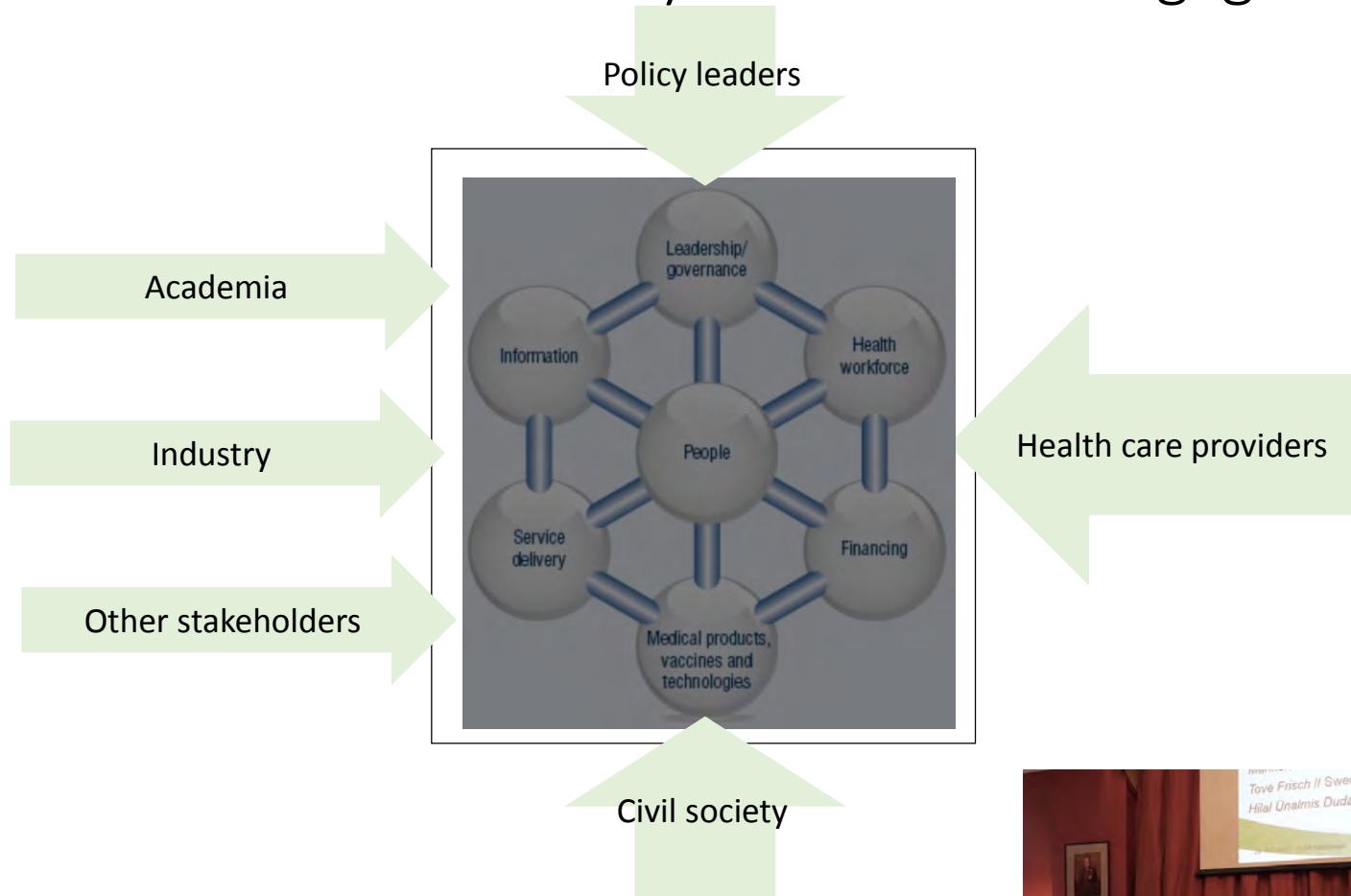
Sources: Lazarus JV *et al.* The micro-elimination approach to eliminating hepatitis C: strategic and operational considerations. *Seminars in Liver Disease*, In press July 2018.

Lazarus JV, Wiktor SZ, Colombo M, Thursz M. Micro-elimination – a path to global elimination of hepatitis C. *Journal of Hepatology*, July 2017.

@JVLazarus

Putting it all together ...

A people-centred health systems approach to HCV elimination with all key stakeholders engaged



Acknowledgements

All authors of all cited studies
and Kelly Safreed-Harmon



Contact: Jeffrey.Lazarus@ISGlobal.org

Dr. Antons Mozalevskis

**Medical Officer, WHO Regional Office
for Europe**



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REGIONAL COMMITTEE FOR EUROPE 66TH SESSION

ELIMINATE ~~HEPATITIS~~

WHO Global Strategy and European Action plan on viral hepatitis. Progress towards elimination by 2030.

Dr Antons Mozalevskis
WHO Regional Office for Europe

2ND EU HCV POLICY SUMMIT “SECURING SUSTAINABLE FUNDING
FOR HEPATITIS ELIMINATION PLANS”



WHO role in viral hepatitis elimination

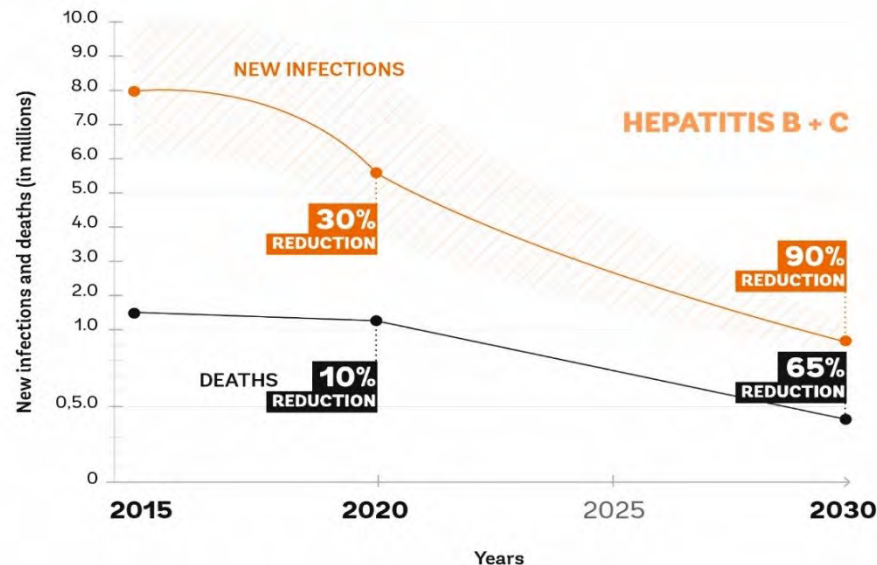
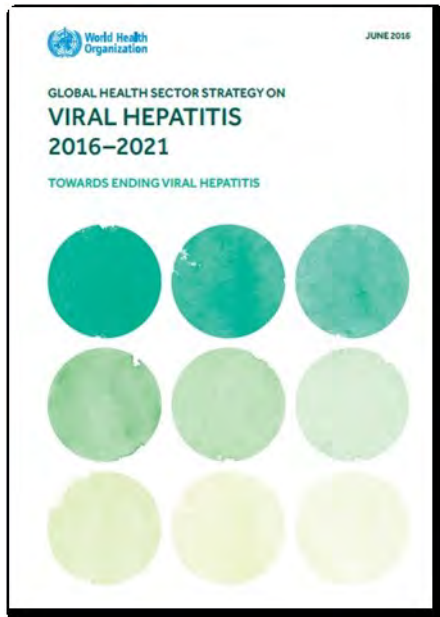
- Global and regional advocacy and leadership
 - Global Strategy and regional action plans
 - World Hepatitis Summits (2015 and 2017)
 - Convening partners
- Normative and policy work and dissemination
- Country support for policy uptake and implementation
- Supporting access to affordable medicines
- Surveillance support and global reporting

Global Health Sector Strategies, 2016–2021



- The three organizing frameworks:
- **Unniversal health coverage (UHC)**
 - **Continuum of health services**
 - **Public health approach**

Global agenda: **elimination** of viral hepatitis as a public health threat by **2030**



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

1.4 mio deaths (in 2015) to under 500,000 deaths (by 2030)

Hepatitis strategy, 2016: elimination by 2030

	Interventions	2030 targets
1. Service coverage	1. Three dose hepatitis B vaccine	90%
	2. HBV PMTCT	90%
	3. Blood and injection safety	100 % screened donations 90% reuse-prevention devices 100% safe injections
	4. Harm reduction	300 injection sets/PWID/year
	5. Testing and treatment	90% diagnosed 80% eligible treated
2. Impact	A. Incidence reduction	90%
	B. Mortality reduction	65%

PMTCT: Prevention of mother to child transmission

PWID: Person who injects drugs



European Action plan on viral hepatitis

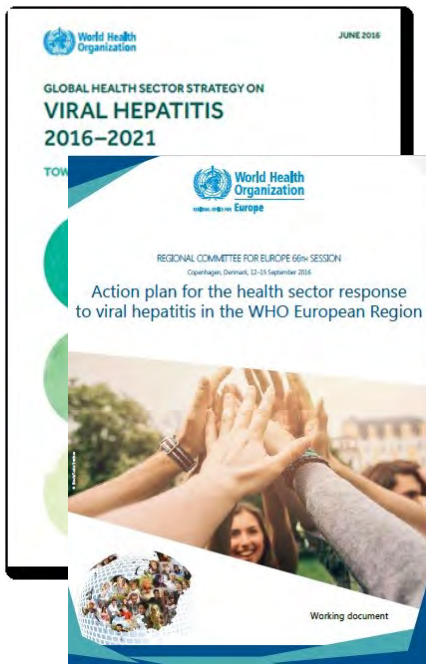
Goal: Eliminate viral hepatitis as a public health threat by 2030

Five strategic directions:

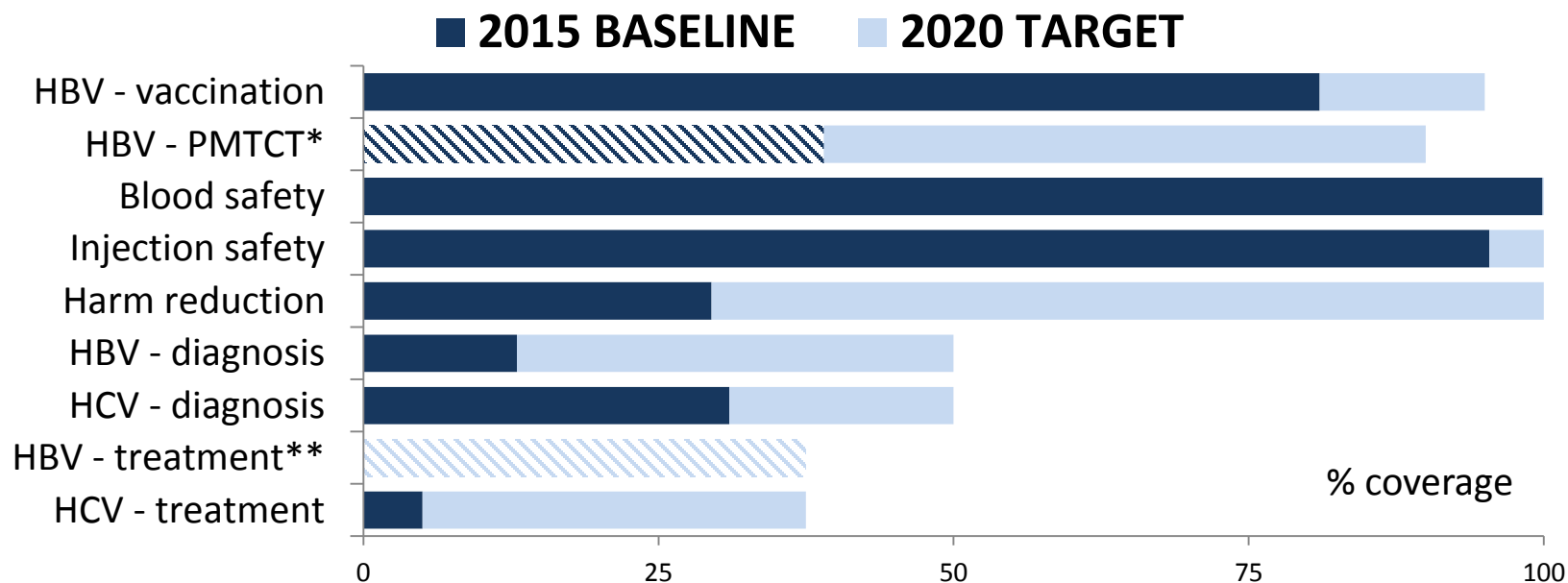
1. Information for focused action
2. **Interventions for impact**
3. **Delivering for equity**
4. **Financing for sustainability**
5. Innovation for acceleration

UHC 3 DIMENSIONS

- the «what»
- the «how»
- the financing



Regional “essential” targets by 2020 on the way to elimination of hepatitis



*Measuring the progress on vertical transmission prevention is limited by data on pregnant women screening coverage

** Measuring the progress on HBV treatment is now limited by the absence of data on the proportion of persons eligible

Towards stronger national plans – for an effective and coordinated response

Global
Health
Sector
Strategy

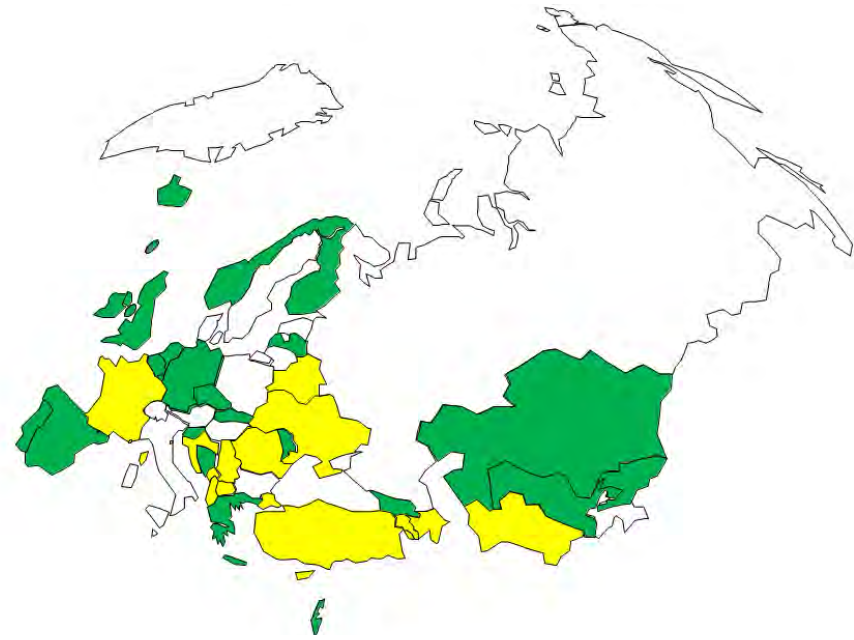
Regional
Action
Plans

National
Strategies
or Plans

- coordinates efforts internally and externally
- an embodiment of commitment
- bring people together for action
- make government offices accountable
- provide a framework for monitoring
- help mobilize internal and external resources

Countries stepping up to eliminate hepatitis

The number of countries with **national hepatitis plans** increased from 13 (in 2013) to 22 (in 2017) in our Region



- Endorsed hepatitis action plans (22 countries)
- Developing hepatitis action plans (14 countries)

Remaining challenges

- Lack of global donors and commitment in many countries
- Data is patchy and monitoring systems are nascent
- Most of the people living with hepatitis still undiagnosed
- Treatment access limited by regulatory barriers and high prices
- Addressing vulnerable / key populations can be a political issue

Monitoring price reductions for DAAs

Opportunities: Intensifying competition to reduce prices

Fig. 3.3. Trends in the lowest reported prices for direct-acting antivirals per 28-day supply, 2016–2017



Note: Prices as reported by DAA producers and countries in the WHO 2016 and 2017 surveys

Source: WHO Progress Report on Access to HCV Treatment, March 2018

Way forward

- Promoting UHC principles and people-centered approach
- A public health approach: simplification, integration, decentralization, equitable access
- Partnerships: governments, civil society and private sector
- Concrete and tailored action in countries, guided by national plans
- Lessons learned from HIV: **avoid** parallels system, separate delivery and financing arrangements
- Bottom line: **integration = sustainability**

Acknowledgments

WHO Headquarters: Dr Marc Bulterys, Dr Yvan Hutin, Dr Philippa Easterbrook, Dr Gottfried Hirnschall, Dr Hande Harmanci

WHO Regional Office for Europe: Dr Masoud Dara, Annemarie Stengaard

Contact:

- mozalevskisa@who.int
- eurohep@who.int

<http://www.euro.who.int/hepatitis>

<http://www.who.int/hepatitis/en/>

Questions & answers



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Keynote address

Chair:

Prof. Minerva Melpomeni Malliori, National and Kapodistrian University of Athens



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“Policy actions to secure long-term funding for hepatitis elimination”

President George A. Papandreou

President of the Socialist International

Former Prime Minister of Greece



George A. Papandreou served as a Prime Minister of Greece from 2009-2011. He was a Member of the Greek Parliament for 24 years (1981-2015). He served in several government posts, as undersecretary of Culture and Minister of Education, before becoming Foreign Minister from 1999-2004.

For his efforts to reform Greece he was named one of the Foreign Policy magazine's TOP 100 Global Thinkers in 2010.

Currently he is the President of the Socialist International, the largest global political family. The SI brings together 153 social democratic, socialist and Labour parties from all continents. Currently, 53 member parties of the SI are in government and numerous represent the main opposition.

First European Union HCV Policy Summit in 2016

Papandreou statements

- In this interdependent world we are facing crises, financial, climate change, pandemics or refugee, that can only be dealt with, if we **cooperate closely.**
- More **political will** to innovate and tackle the deeper challenges of our health systems.
- The added value of the EU could easily be enhanced if the 28 countries decided to support a major **campaign to eradicate HCV.**

First European Union HCV Policy Summit in 2016

Papandreou statements

- The more we have **active civil societies** the more politicians, business and our health services will listen and our citizens will benefit.
- Finally I would call on you to advocate the **creation of a fund**, which will finance a Europe wide campaign for the complete eradication of HCV.

Let's act now!

President George A. Papandreou

**President of the Socialist International,
Former Prime Minister of Greece**



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Session 2:

The cost of HCV Elimination

Chairs:

Prof. Francesco Negro, European Association for the Study of Liver

Prof. Sharon Hutchinson, Glasgow Caledonian University



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Dr. Zobair Younossi

**Chairman, Department of Medicine,
Inova Fairfax Medical Campus**



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Prof. Sylvie Deufic-Burban

**French National Institute of Health and
Medical Research (INSERM)**



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Dr. David Tordrup

**WHO Consultant, WHO Collaborating
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Regulation, Utrecht University**



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Prof. Jagpreet Chhatwal

Assistant Professor, Harvard Medical School



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Is Hepatitis C Elimination Cost Saving?

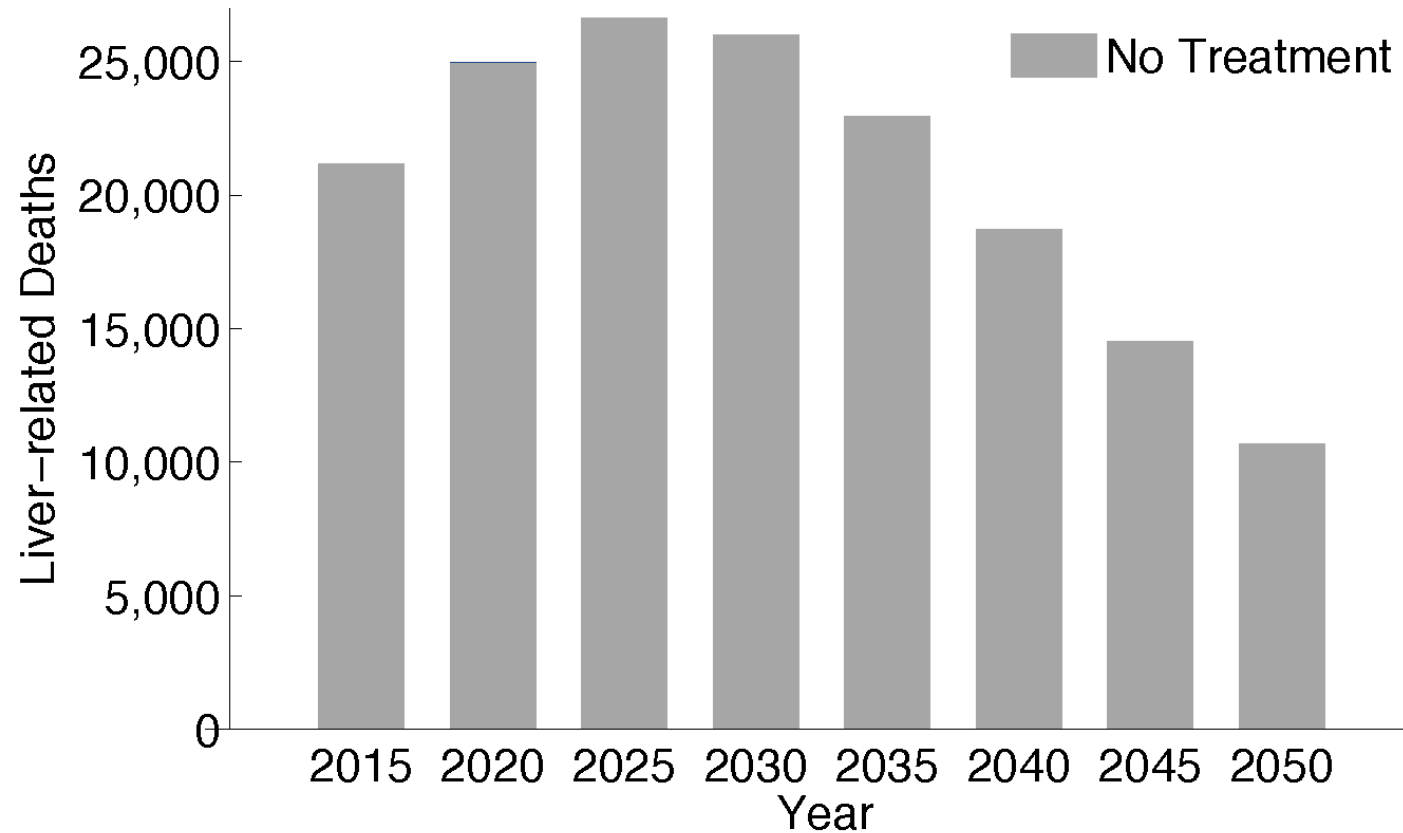
Jagpreet Chhatwal, PhD

Massachusetts General Hospital
Harvard Medical School
Boston, USA

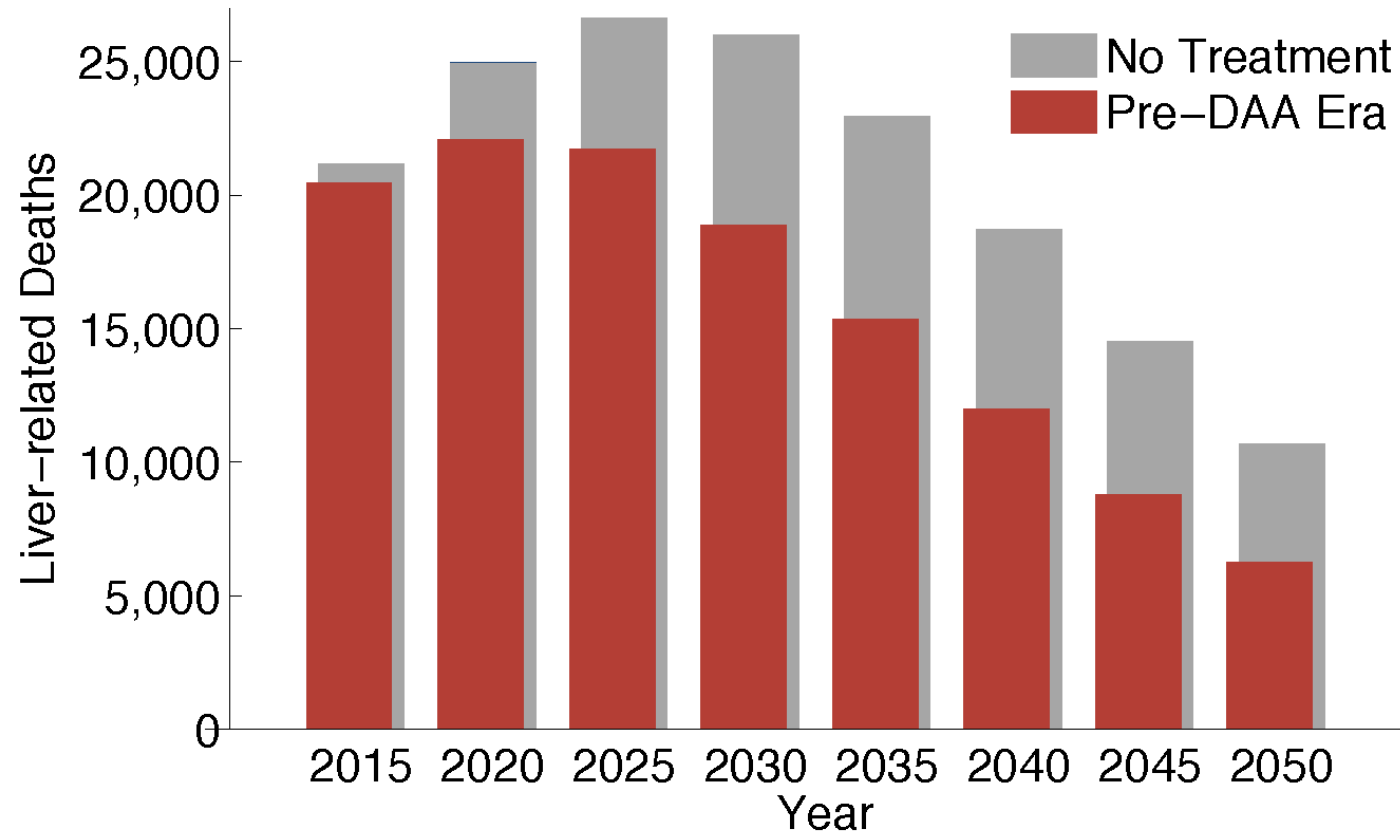
Relevant Questions of Interest...

- How the use of new therapies is expected to reduce HCV disease burden?
- Are new therapies cost-effective and/or cost-saving?
- What's the cost of eliminating HCV?

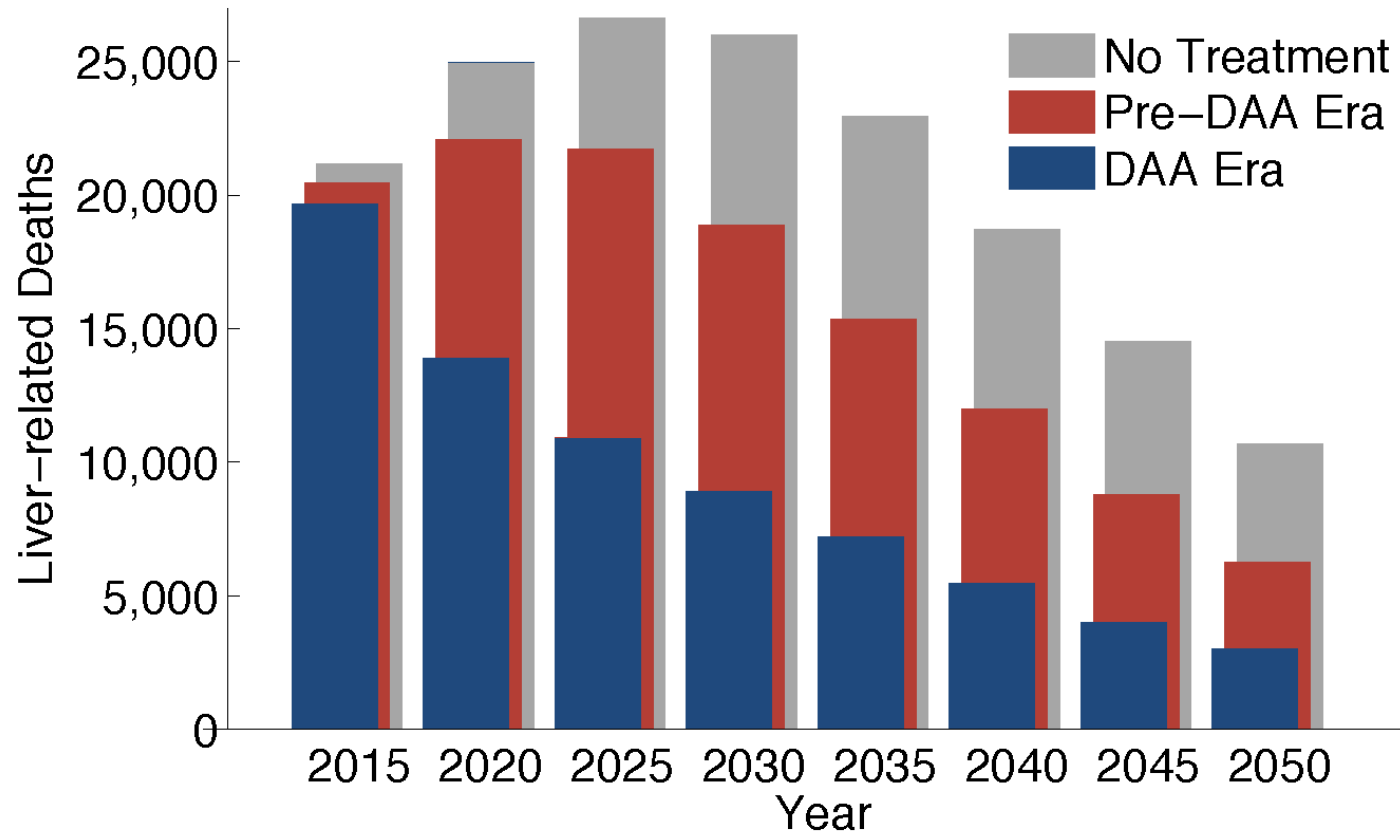
Liver-Related Deaths in the Era of New Antivirals: United States



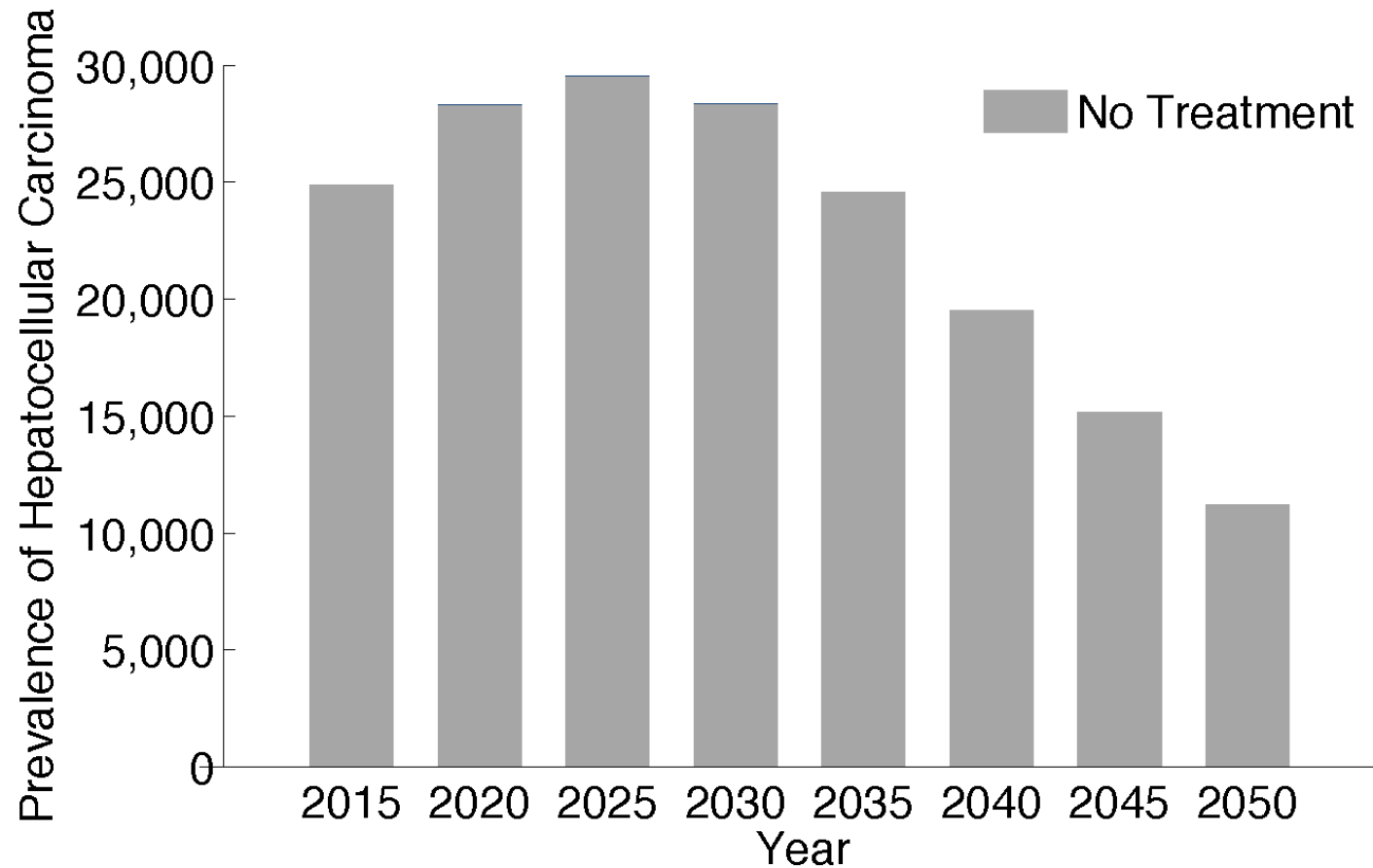
Liver-Related Deaths in the Era of New Antivirals: United States



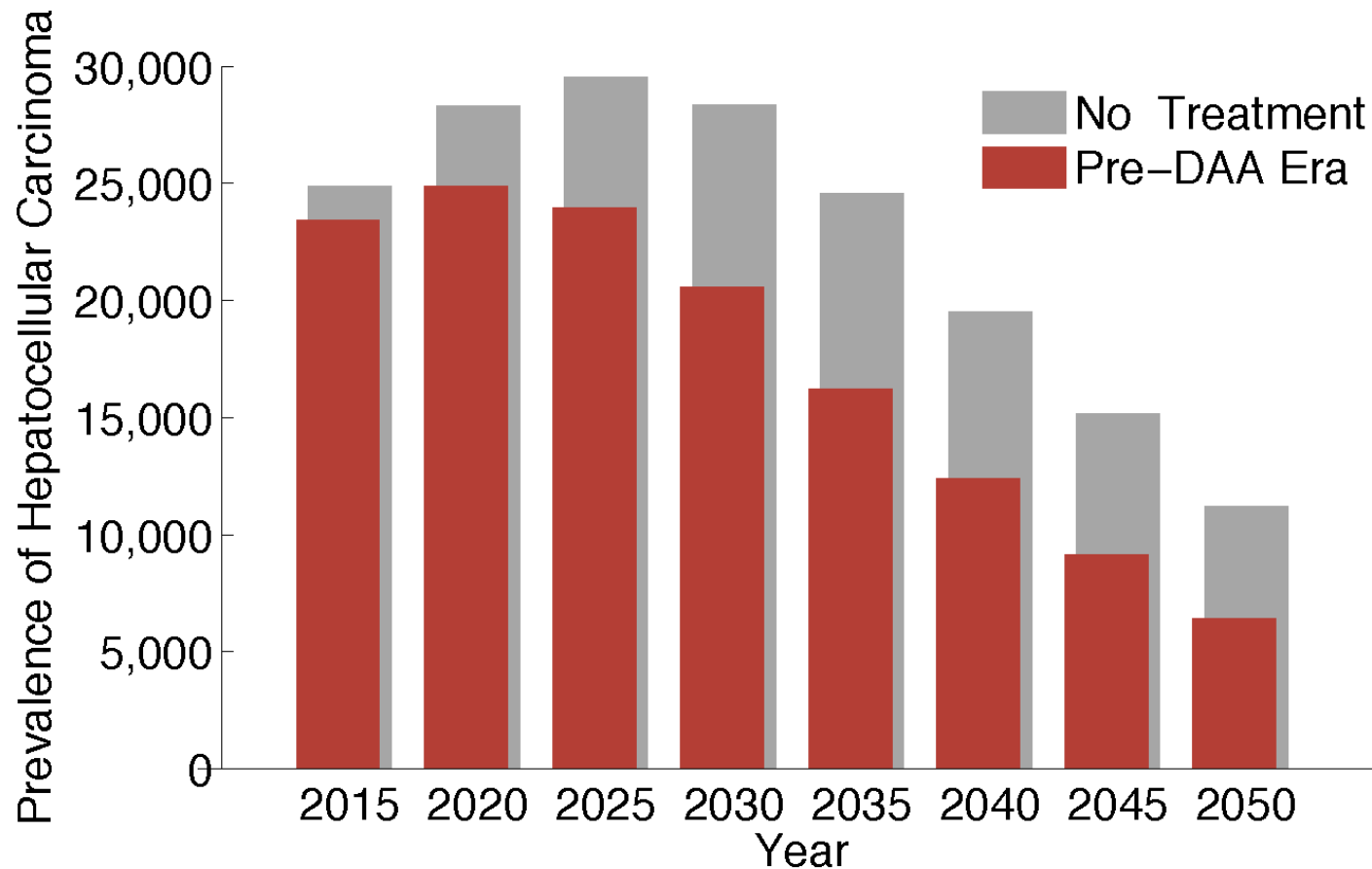
Liver-Related Deaths in the Era of New Antivirals: United States



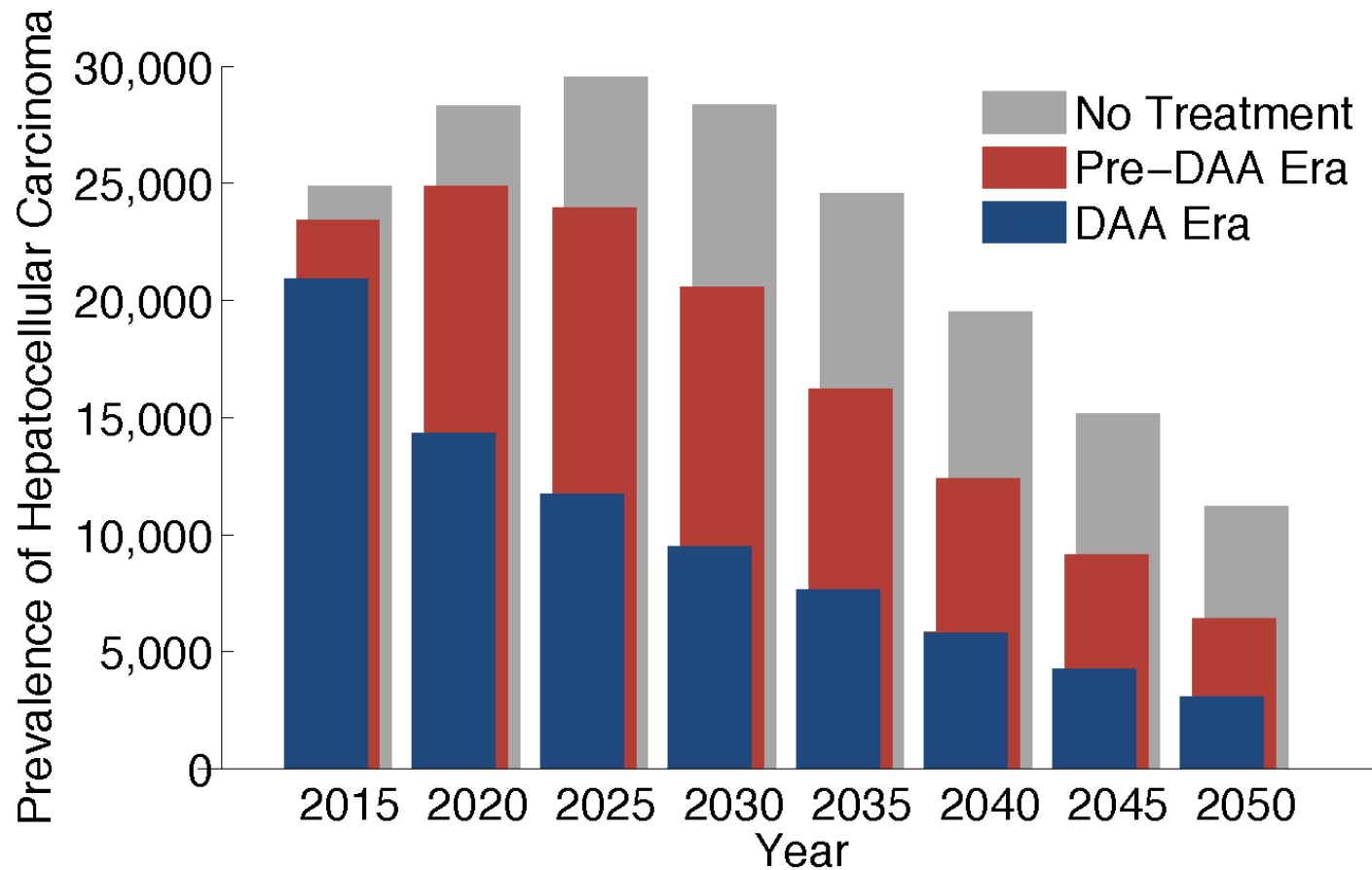
Liver Cancer in the Era of New Antivirals: United States



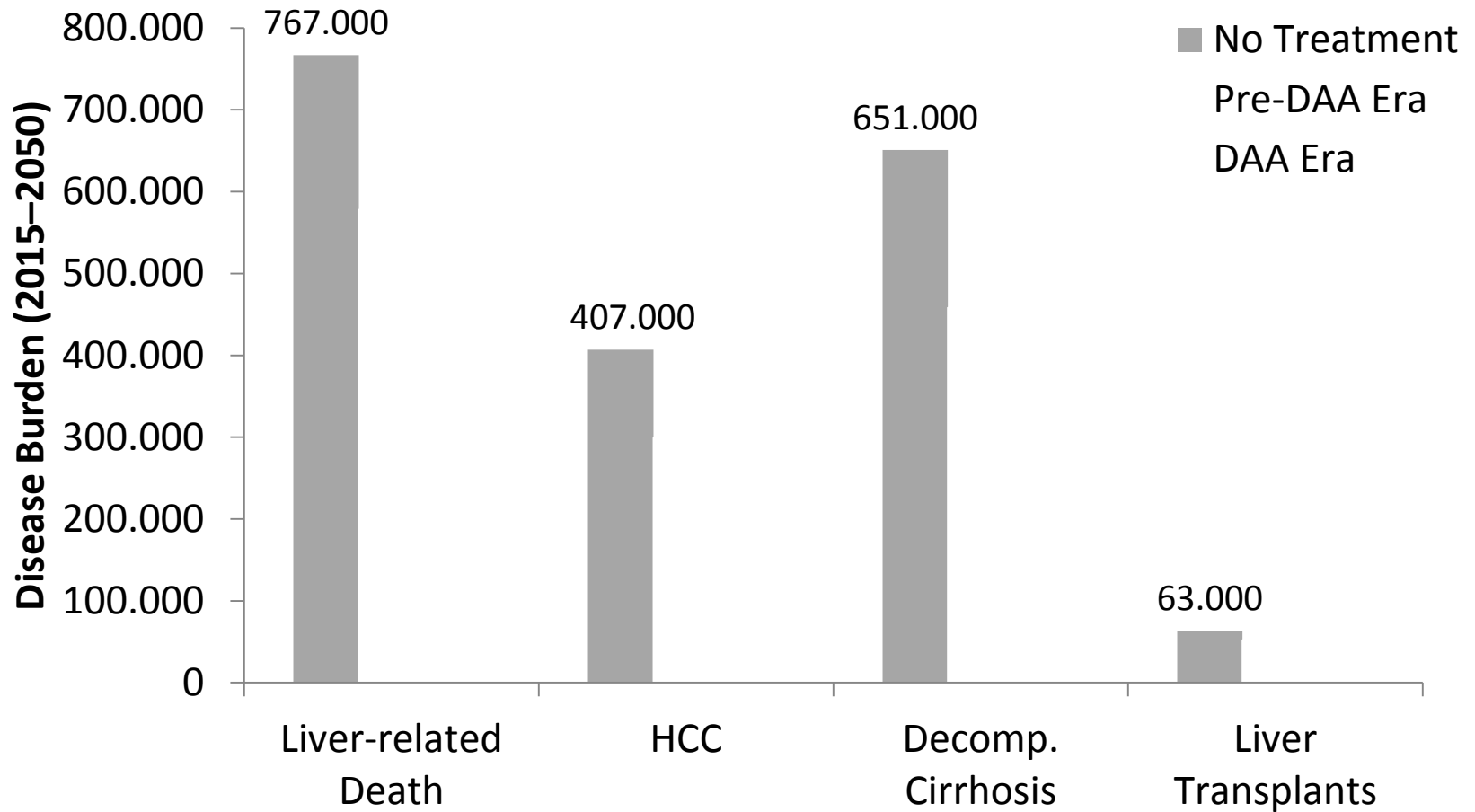
Liver Cancer in the Era of New Antivirals: United States



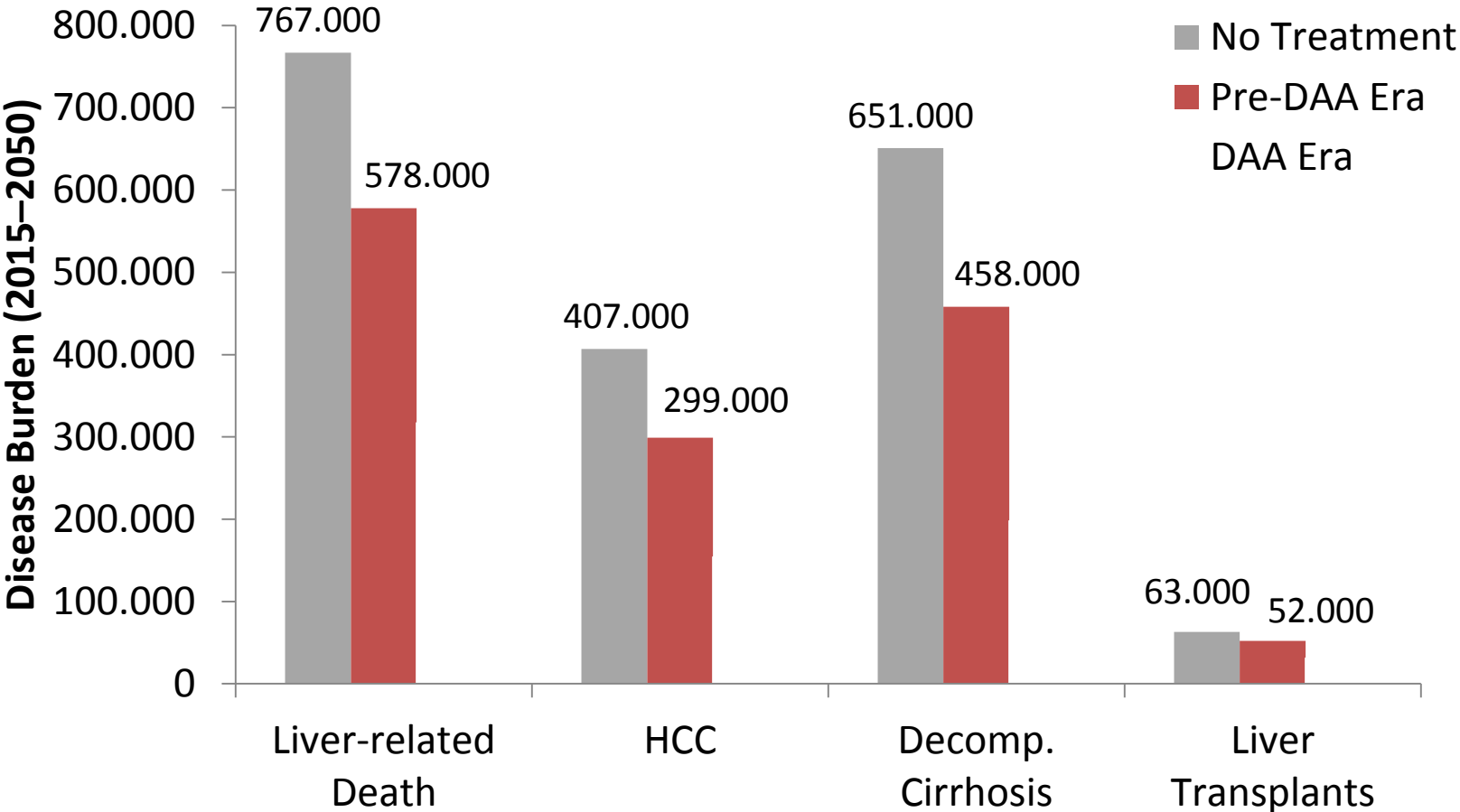
Liver Cancer in the Era of New Antivirals: United States



HCV-Associated Disease Burden (2015–2050)

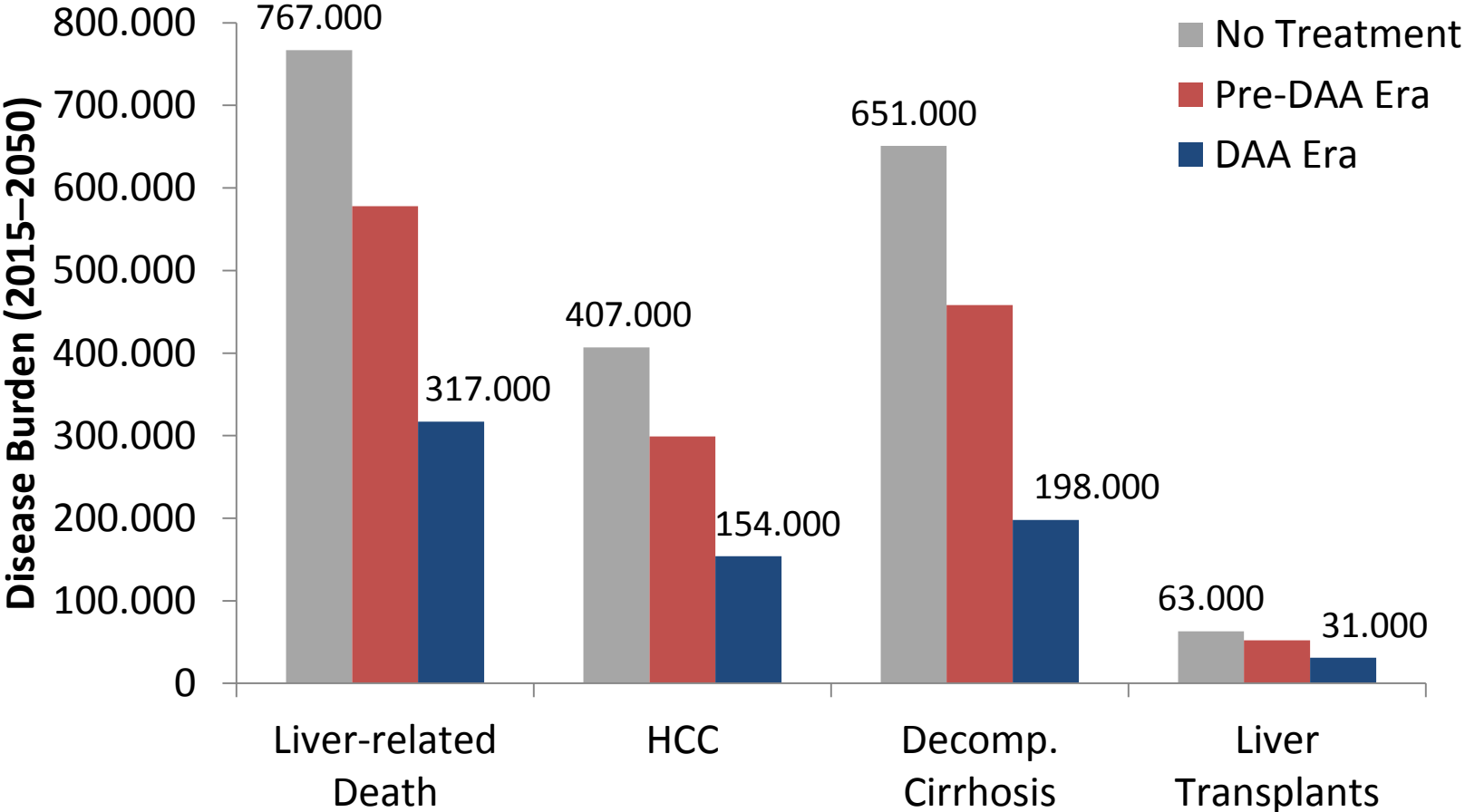


HCV-Associated Disease Burden (2015–2050)



20–30% reduction in HCV-associated disease burden

HCV-Associated Disease Burden (2015–2050)



50–70% reduction in HCV-associated disease burden

Cost of HCV Treatment

The Elephant in the Room...



Is \$1000-a-pill Price Justified?



\$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices

by RICHARD KNOX

December 30, 2013 3:22 AM



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NEWS

February 18, 2014

Screening urged for Hepatitis C but drug costs are prohibitive

Formulations

Gilead is not the original developer of Sovaldi, its new Hepatitis C medication that will cost \$84,000 for a 12-week course of treatment; instead, it bought the drug developer, rival company Pharmasset, for \$11 billion cash in 2011. Gilead now seeks a bon

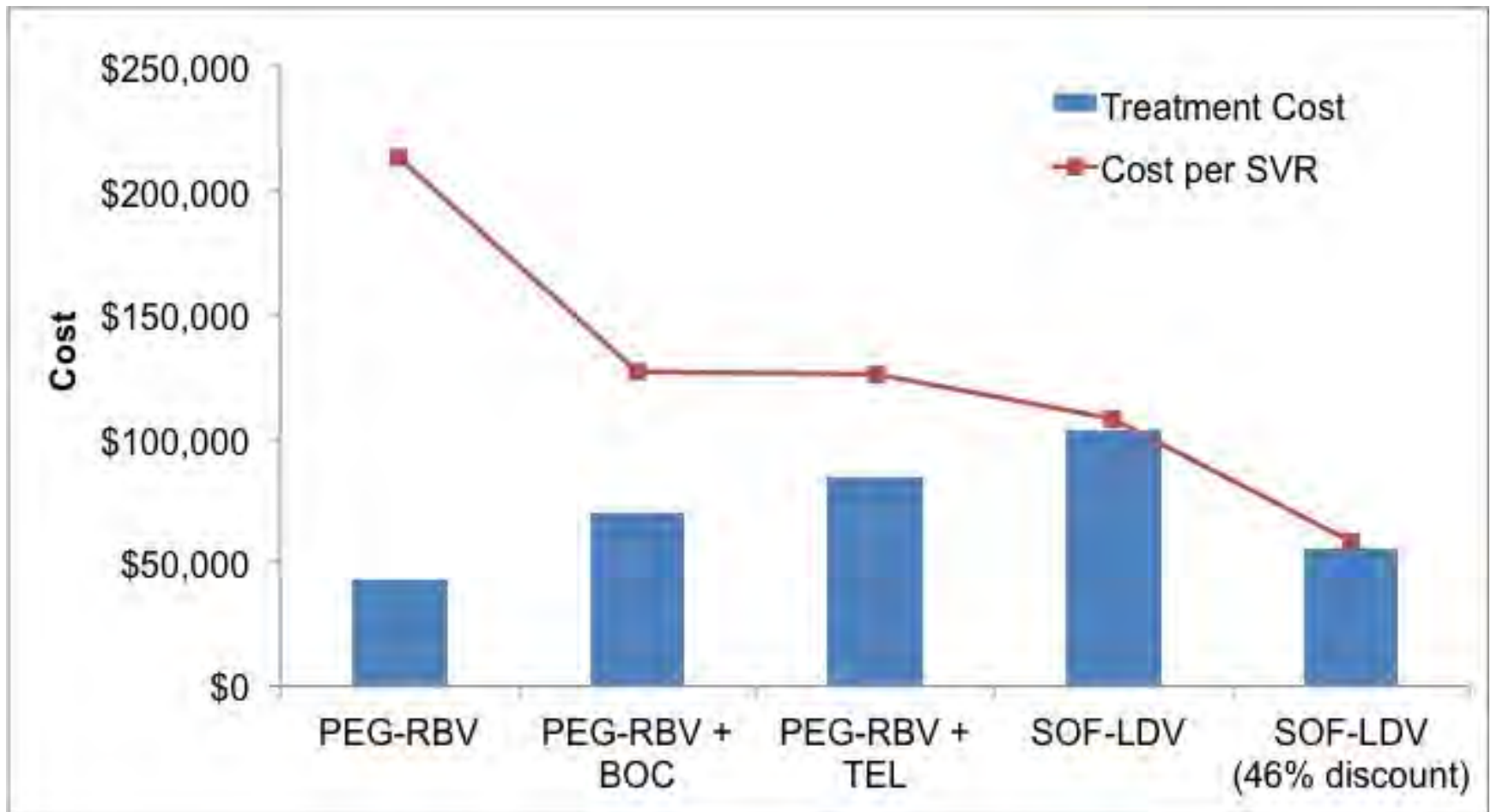
January 29, 2014

the Price Right?

Is HCV Treatment Cost-Effective/Saving?

- Cost-effective \neq cost savings
- Cost-effective \neq affordable
- “**Cost-effective**” implies that we are willing to spend additional money to gain additional health benefits
- “**Cost-saving**” implies that we will gain health benefits by implementing the intervention, and we will save money as well

HCV Treatment Costs Have Decreased



Chhatwal J, et al. Why We Should Be Willing to Pay for Hepatitis C Treatment. *Clin Gastroenterol Hepatol*. 2015;13(10):1711-1713.

What is the Value of HCV Treatment?

What is the lifetime treatment cost?

- **HIV treatment**¹ = \$315,000
- **Primary biliary cholangitis** (obeticholic acid)² = \$900,000
- **Hepatitis C** treatment (oral DAAs) < \$30,000

How much would it cost to gain 1 additional quality-adjusted life year?

- **HIV treatment**³ < \$30,000 (cost-effective)
- **Primary biliary cholangitis** (obeticholic acid)² = \$190,000 (not cost-effective)
- **Hepatitis C** treatment (oral DAAs)⁴ :

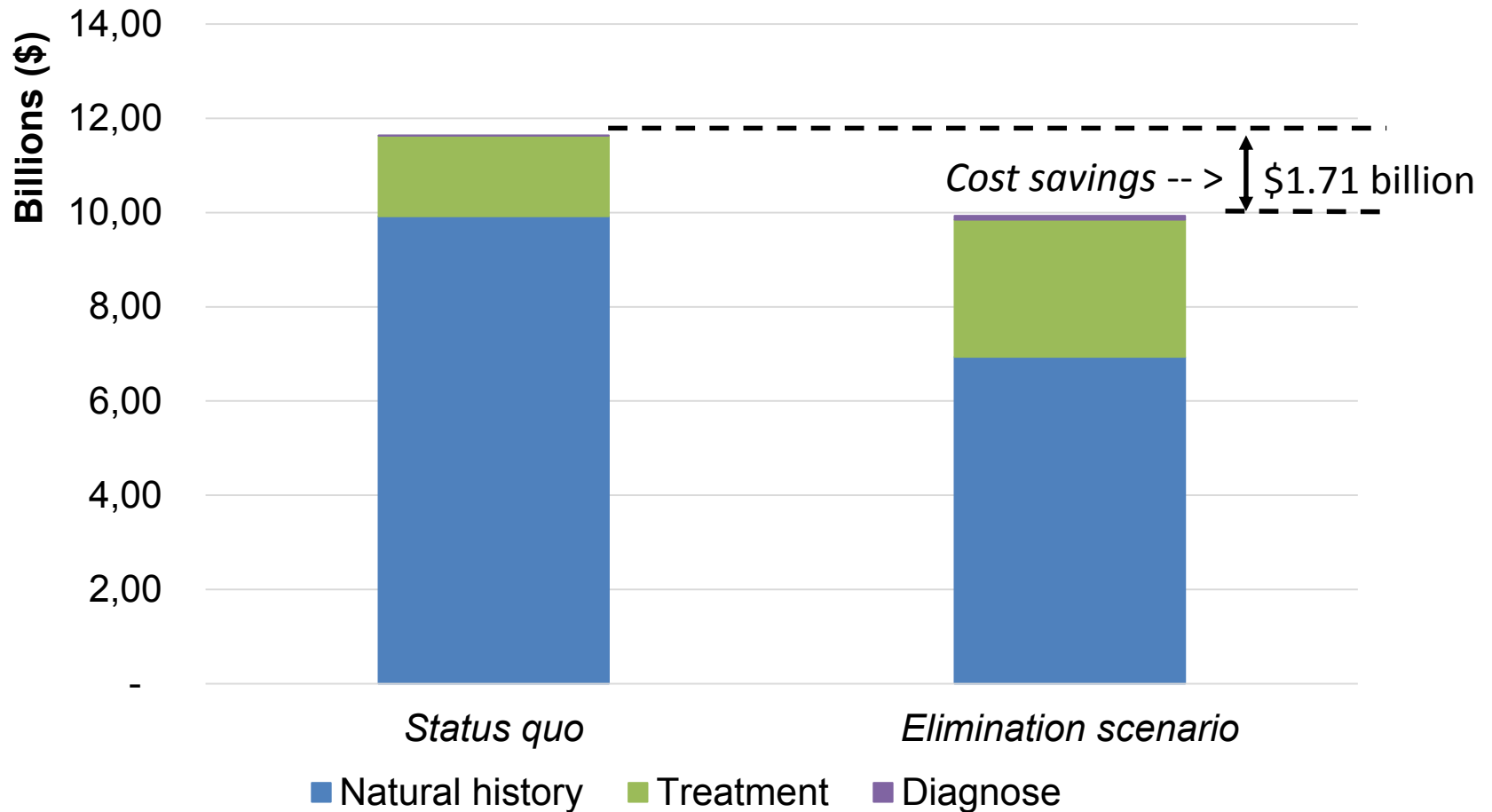
¹Schackman 2006 *Med Care*. ²Samur 2017 *Hepatology*; ³Walensky 2007 *Clinical Inf Dis*. ⁴Chhatwal 2017 *Clinical Gastro & Hep*

HCV Treatment is Cost-Saving

The more we treat, the more we save!

Cost of HCV Management: UK

Cost of HCV Elimination vs Status Quo: United Kingdom



Summary

- HCV elimination is feasible and will save lives
- Initial investment is needed to eliminate HCV
 - Resources spent on HCV elimination provide a good value for money and will result in cost-savings

Questions & answers



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Session 3:

Innovative financing

Chairs:

Prof. Markus Peck-Radosavljevic, Klinikum Klagenfurt am Wörthersee

Prof. Dr. Nurdan Tözün, Acıbadem University



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INNOVATIVE FINANCING OF HCV ELIMINATION

Prof. Markus Peck-Radosavljevic

Prof. Dr. Nu

Innovative financing of HCV Elimination Prof. Jagpreet Chhatwal

***Financing solutions for hepatitis
elimination in low and middle-
income countries***

Dr. Homie Razavi,



civil society organisations



individual citizens



European Union institutions



healthcare professionals



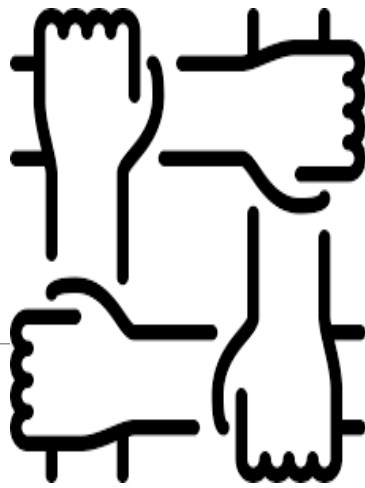
private sector



researchers



EMCDDA



Elimination of HCV requires a strong collaboration of stakeholders

The plan for HCV elimination should be **achievable**, **sustainable** and **time framed**

One of the crucial factors is an **adequate funding** in continuum to support the HCV elimination initiative

Financing remains a large gap and making the treatment affordable is still a challenge for many European, Mediterranean and Eastern European countries

HOW TO REACH THE GLOBAL TARGET OF ELIMINATION ?

Financial matters should not be a barrier to get access to treatment

Out-of pocket payments in LMIC can compromise access to treatment

National health authorities should place hep C among priority national health issues

Adequate and realistic plans to increase resources should be planned (increased revenue by taxes ,allocation of more funds for health or external funding)

KEY ELEMENTS FOR SUCCESS

Awareness among policy makers

Strong political will to eliminate HCV

National plan to reach the target

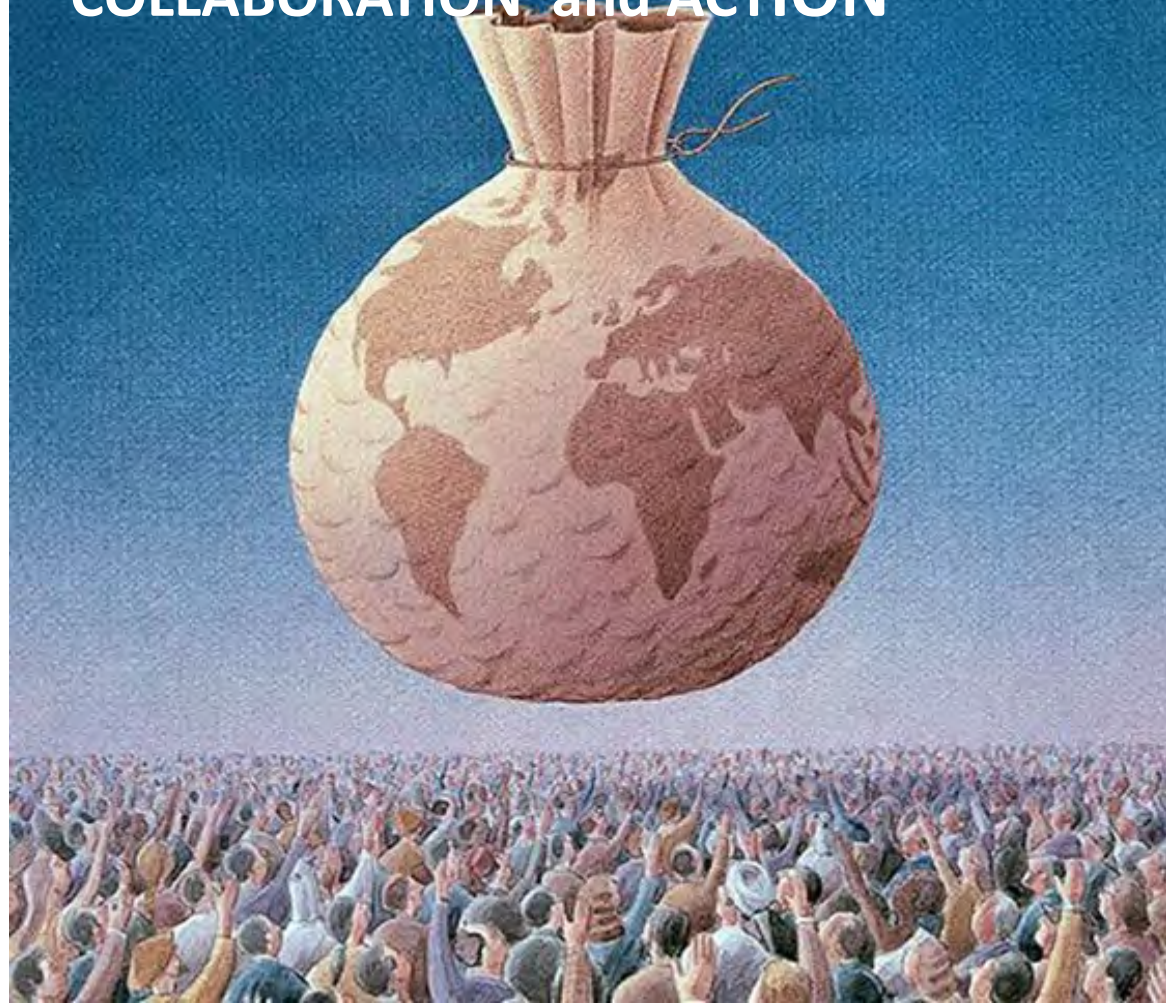
Investment for action and adequate funding

Pan-European collaboration

Special budgetary plans for LMIC

A WORLD FREE OF HEPATITIS C

Its not only a matter of banknotes,
coins or loans but one of RESOLUTION,
COLLABORATION and ACTION



Objectives of This Session

- To raise awareness about the financial challenges that the HCV elimination plan is facing
- To bring up new, innovative solutions for a sustained, realistic and efficient financing of the HCV elimination program
- To provide concrete plans for funding HCV elimination in Europe and beyond
- To discuss the best solution for elimination which will be applicable in all countries with high GDP and low/middle income

Prof. Jagpreet Chhatwal

Assistant Professor, Harvard Medical School



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Innovative Financing of HCV Elimination

Jagpreet Chhatwal, PhD

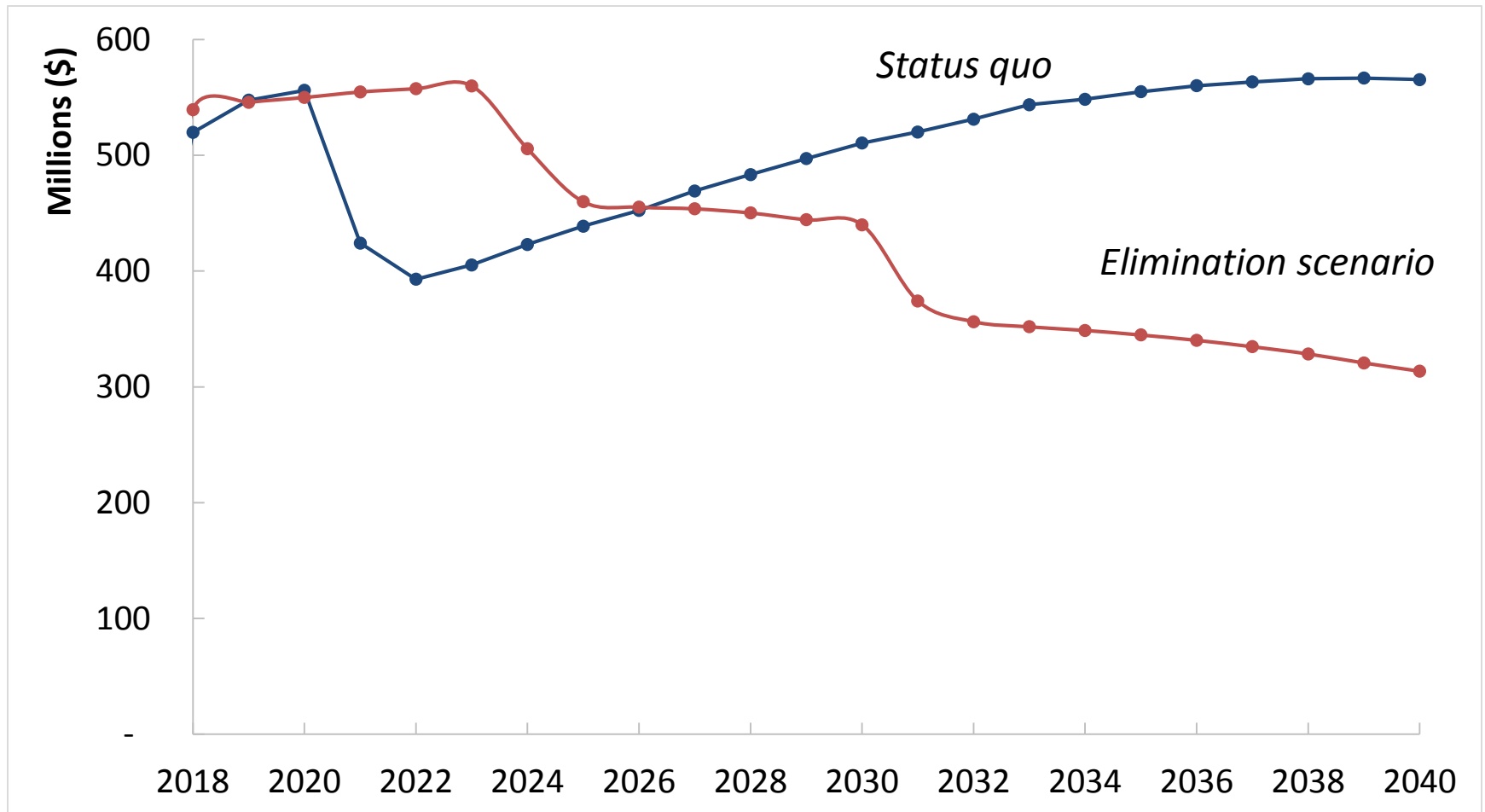
Massachusetts General Hospital
Harvard Medical School
Boston, USA

Outline

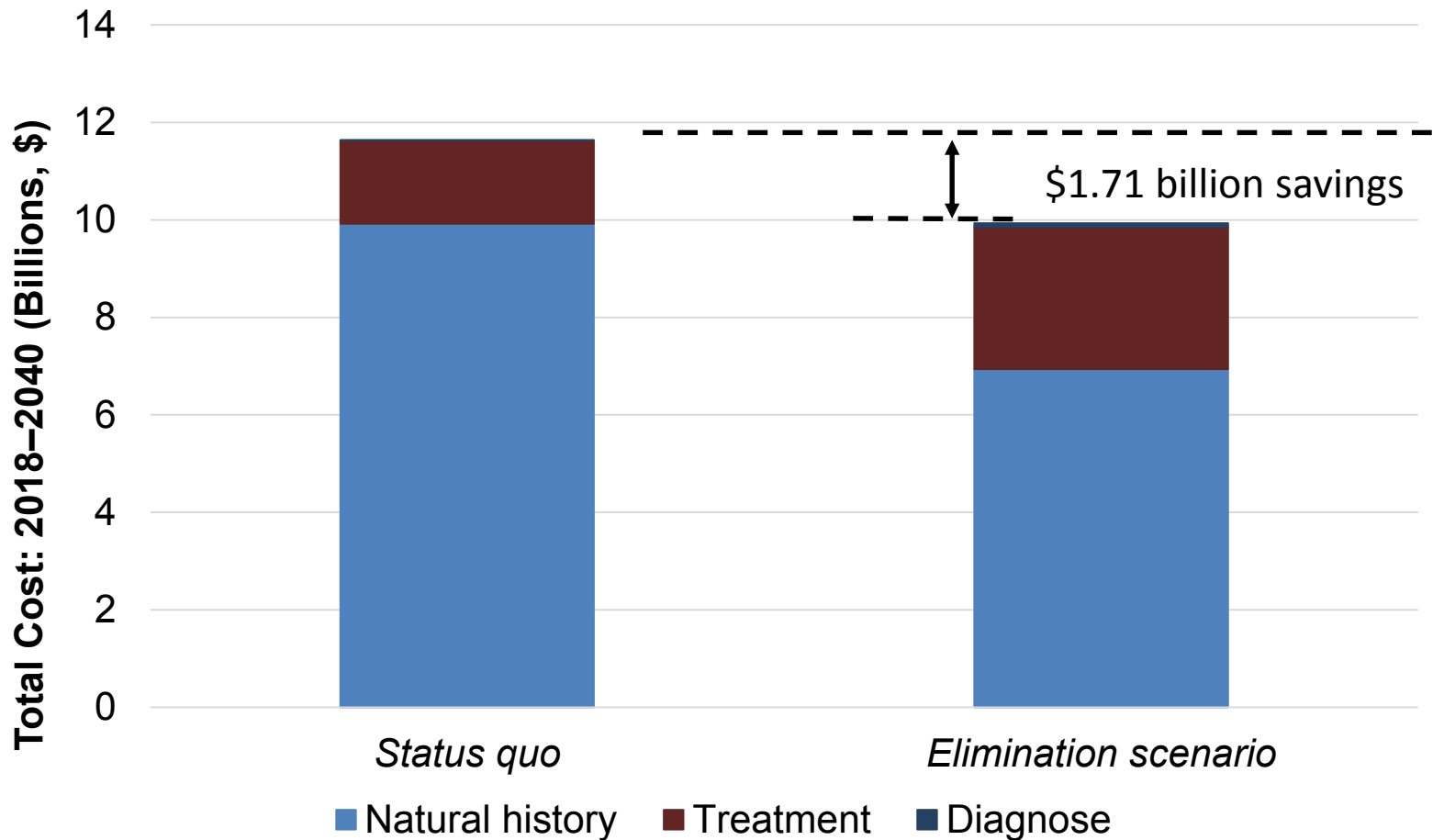
- Cost of HCV elimination in United Kingdom and Pakistan
- Challenges of financing
 - WHO's global health sector strategies for viral hepatitis
- Innovative solutions: financial bonds

Cost of HCV Elimination

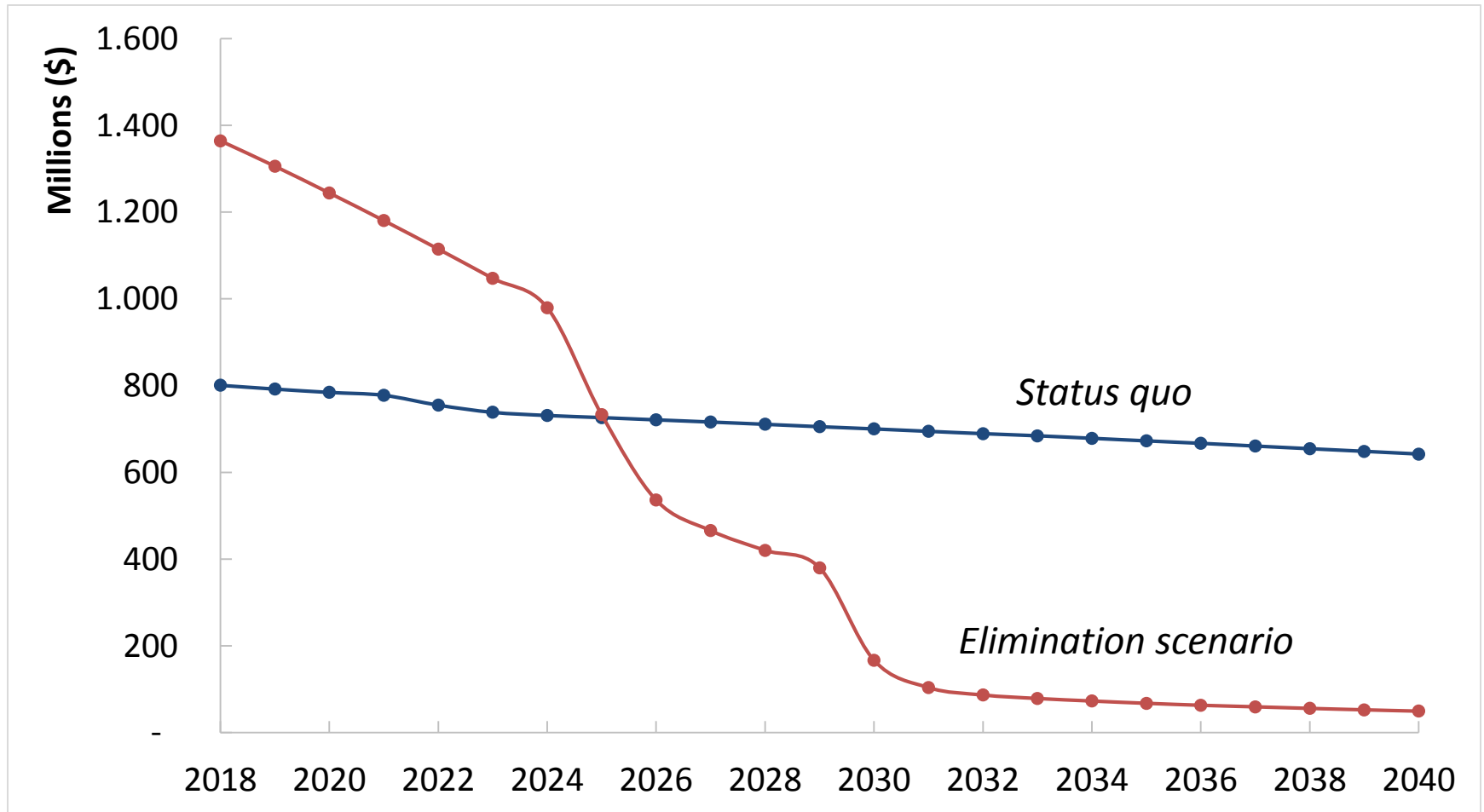
Cost of HCV Elimination vs Status Quo: United Kingdom



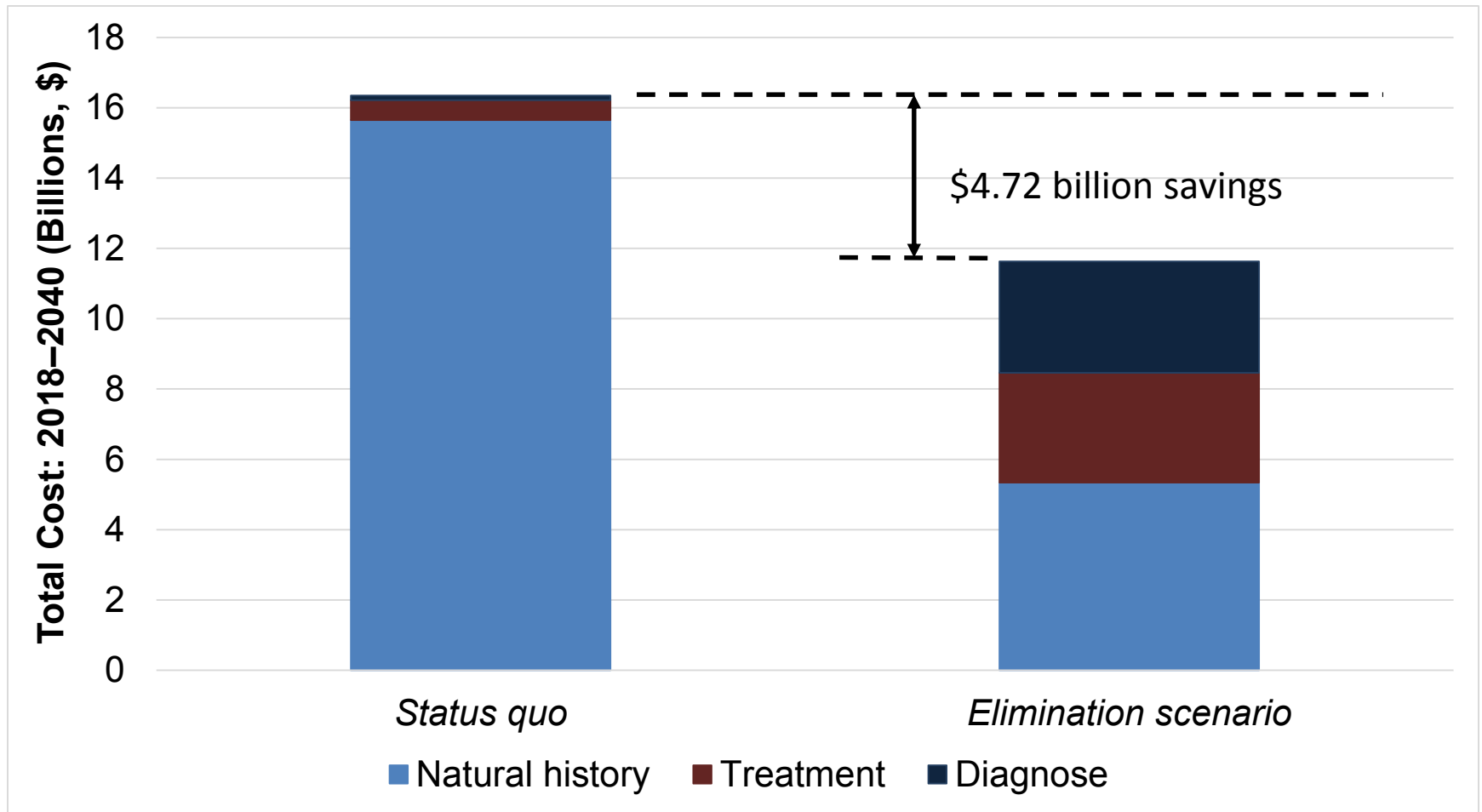
HCV Elimination in the United Kingdom is Cost Saving



Cost of HCV Elimination vs Status Quo: Pakistan



HCV Elimination in Pakistan is Cost Saving



Challenges and Directions

Challenges

- Unlike the other major communicable diseases, such as HIV, tuberculosis and malaria, there is no “Global Fund” for viral hepatitis
- Most countries do not have dedicated hepatitis budgets or programme
- Therefore, new sources of funding will be required for countries to launch, accelerate and sustain public health responses to eliminate viral hepatitis
 - these resources will need to be substantial to meet the elimination targets

WHO Global Health Sector Strategies for Viral Hepatitis:

Strategic direction 4 – Financing for sustainability

- The strategy defines a set of priority actions for countries to undertake, and counterbalances this with a set of priority actions for WHO to undertake, in support of countries
- **Innovate funding approaches needed to increase revenue**
 - New sources of funding will be required to fund sustainable scale-up of programmes
- **Provide financial risk protection**
 - Treating HCV with new therapies, and providing care for cirrhosis and cancer can be very expensive and is unaffordable for many people.
 - Making hepatitis services more affordable — especially by reducing **out-of-pocket** expenses associated with using them
- **Improving efficiency in the use of health system resources** to enable greater effective coverage of hepatitis services,
 - by reducing the costs of medicines and diagnostics
 - by reducing duplication of underlying subsystems with other programmes

Tools to Assess Cost and Value of HCV Treatment

World Health Organization

Home Hepatitis C Team About Hep C Calculator Contact

MGH 1811

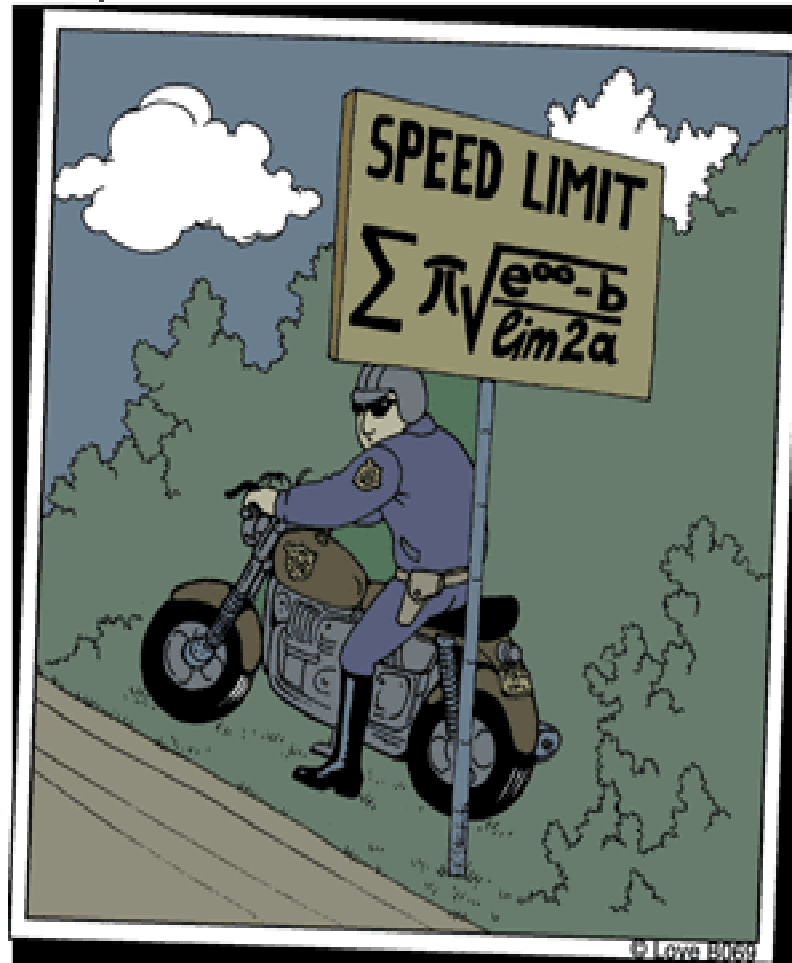
Institute for Technology Assessment

Hep C Calculator

Global Cost-effectiveness Analysis of Hepatitis C Treatment

START

Cost-Effectiveness Analysis is Complex!



What is *Hep C Calculator*?

- **Online, interactive tool** to evaluate the cost-effectiveness of hepatitis C treatment
 - Phase I: 28 WHO focus countries representing 70% of the global burden
- Standardized methods to assess the value of HCV treatment
- Price of antivirals at the local level and over time
- Healthcare costs at the local level
- *Hep C Calculator* can help in price negotiations

Interactive Model Inputs

Select a Country

Pakistan

Cost Inputs (US Dollars)

Cost of treatment and testing

4-week DAA regimen: 15

Diagnosis of chronic HCV: 125

Assessment of HCV treatment response: 25

Annual cost of health state

F0-F2 fibrosis: 50

F3 fibrosis: 80

Compensated cirrhosis: 120

Decompensated cirrhosis: 500

Liver cancer: 15000

Use WHO disability weights to calculate QALYs

Reset Costs **Update Costs**



Population Profile

Select an age: 35

Fibrosis states distribution (sum=101%)

F0 %	F1 %	F2 %
34	31	14

F3 %	Cirrhosis %
13	9

Fibrosis Scores

Reset **Update**

Show genotype distribution

HCV Genotypes

100% -
75% -
50% -
25% -
0% -

G1 G2 G3 Others

Cost-Effectiveness Results in Real Time

Figure 1: Discounted QALYs Lived

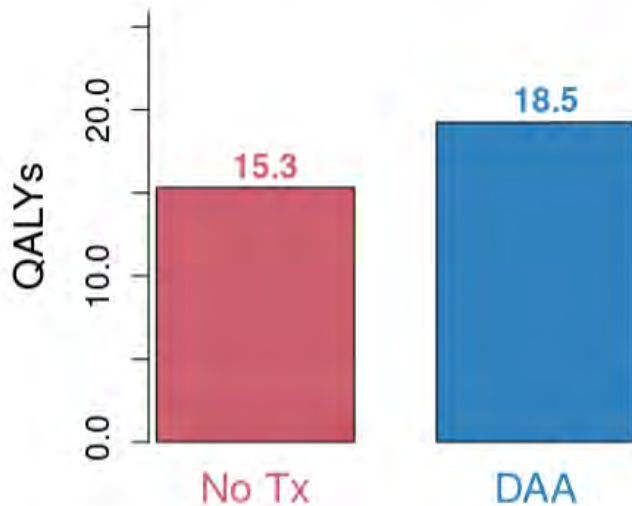
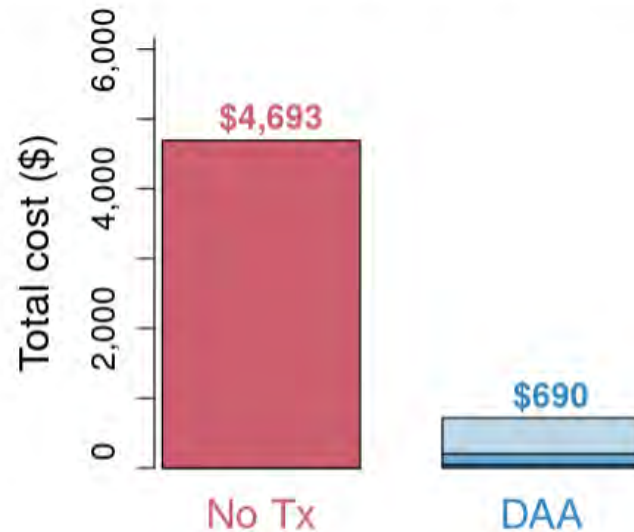


Figure 2: Total Discounted Lifetime Healthcare Costs



- No Tx: Disease management cost
- DAA: Treatment cost
- DAA: Testing cost
- DAA: Disease management cost

Abbreviations: Tx, treatment; DAA, direct acting anti-viral.

Innovative Financing Options

Innovative Financing for HCV Elimination

- Characteristics of HCV financing
 - Investment is needed over a long period of time (e.g., providing antiviral treatment until 2030)
 - Because HCV is a slow progressive disease, the return on investment will accrue after a long time
- Financial bonds
 - Bond finance can be used to effectively transfer the risks associated with long-term spending commitments from governments to investors
 - Through bond finance, not only can governments release money for public spending, but the maturity period can be adjusted to the timeframe in which the investment produces the desired social/economic benefit

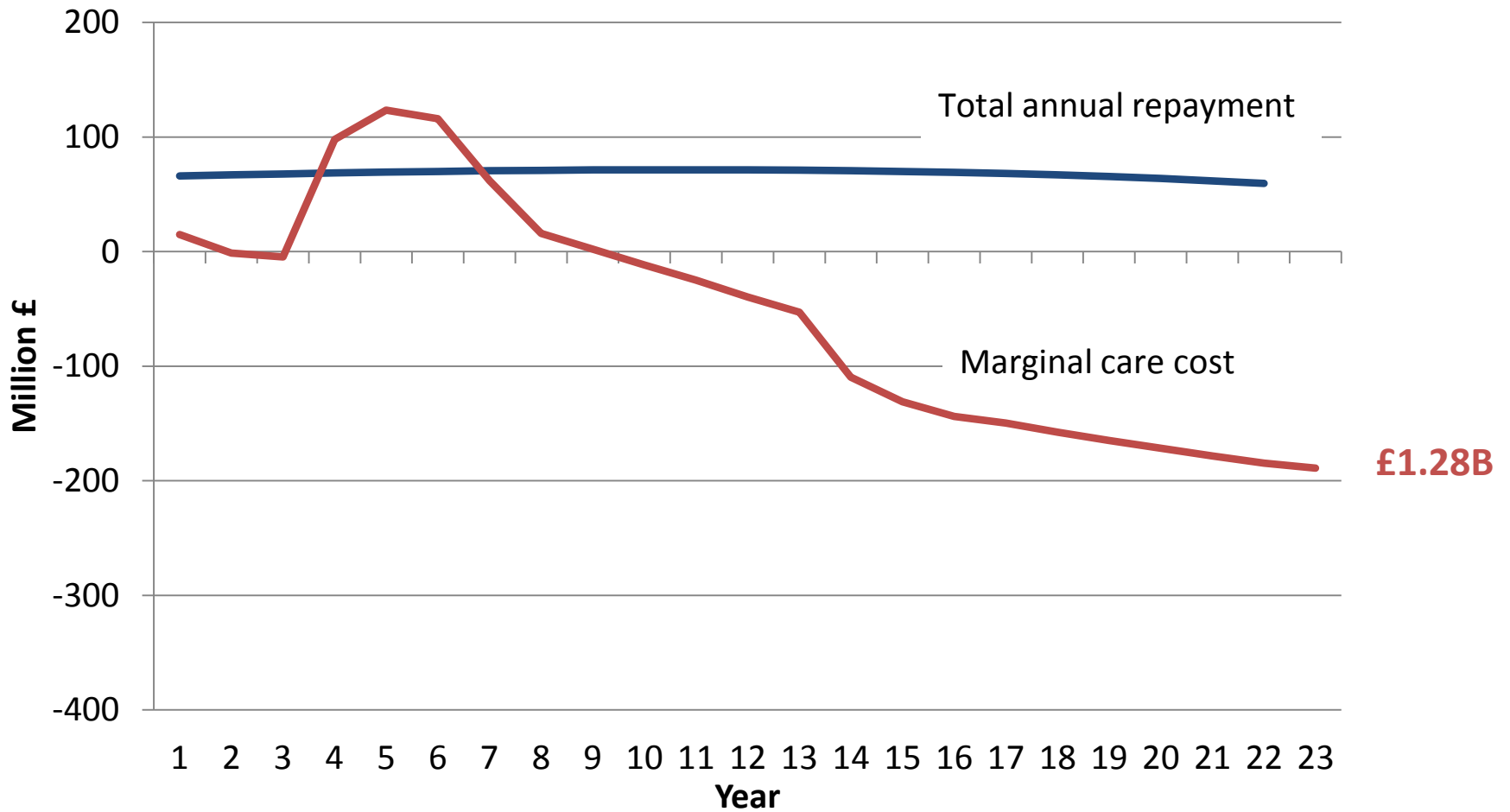
Innovative Financing Options

- Commercial bonds
 - Widely used in the public sector for funding infrastructure projects like roads, schools and bridges, and other ‘social investments’
 - Green bonds: used to fund a variety of local enterprises and initiatives that can contribute to “green” projects (e.g., renewable energy, clean water)
 - World Bank issued a bond that is linked to Sustainable Development Goals (SDG)
- Vaccine bonds
 - *The International Finance Facility for Immunisation (IFFIm)* was created by France, the UK and other European countries in 2006 to sell vaccine bonds to raise finance for the GAVI Alliance
- Social Impact bonds
 - a contract with the public sector in which a commitment is made to pay for improved social outcomes that result in public sector savings (e.g., social bond for rehabilitation of incarcerated people and to reduce recidivism)

“HCV Elimination” Bond Exercise

- Case study of the United Kingdom
 - If 10 million bonds sold at £100
 - Cash raised: £1 billion
 - Years to maturity = 22 years (2018–2040)
 - Coupon interest rate = 3%
 - Annual inflation rate = 3.5%

“HCV Elimination” Bond



Summary

- Innovative funding mechanisms are needed to help achieve HCV elimination
- Money spent on HCV elimination provides a good return on investment
 - Both in terms of deaths prevented and economic savings
- Financial bonds could provide a mechanism to raise funds to eliminate HCV a public health threat
 - The more we treat, the more lives saved and more economic savings

Acknowledgment

- Angelos Hatzakis
- Ann Fox
- Michael Smith
- Rob Walton

Thank You!

Dr. Homie Razavi

**Managing Director, The Centre for
Disease Analysis Foundation**



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Catalytic Financing of Hepatitis Elimination in Low and Middle Income Countries

A Step Towards Universal Healthcare

H. Razavi, PhD, MBA

June 6, 2018



@CDAFound

hrazavi@cdafound.org



CDA
FOUNDATION

The low and middle income countries are not homogenous – we have identified three segments



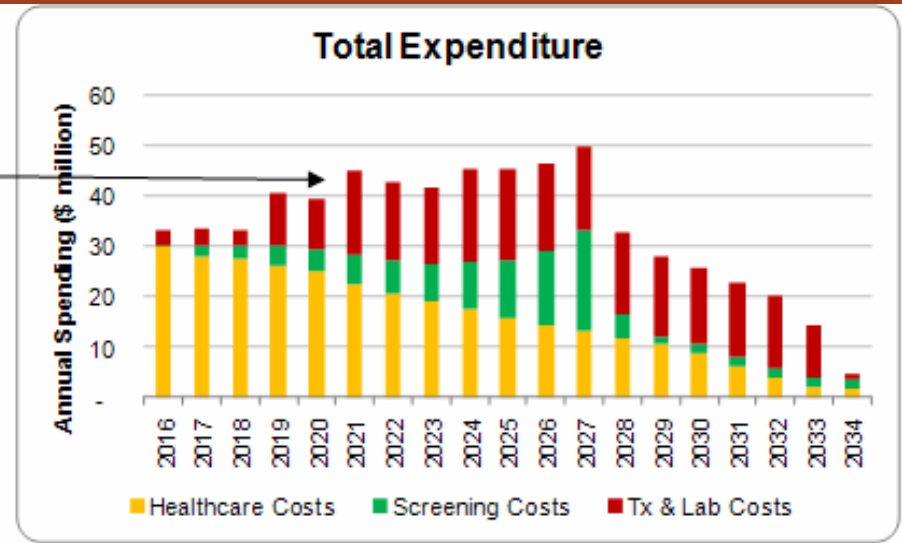
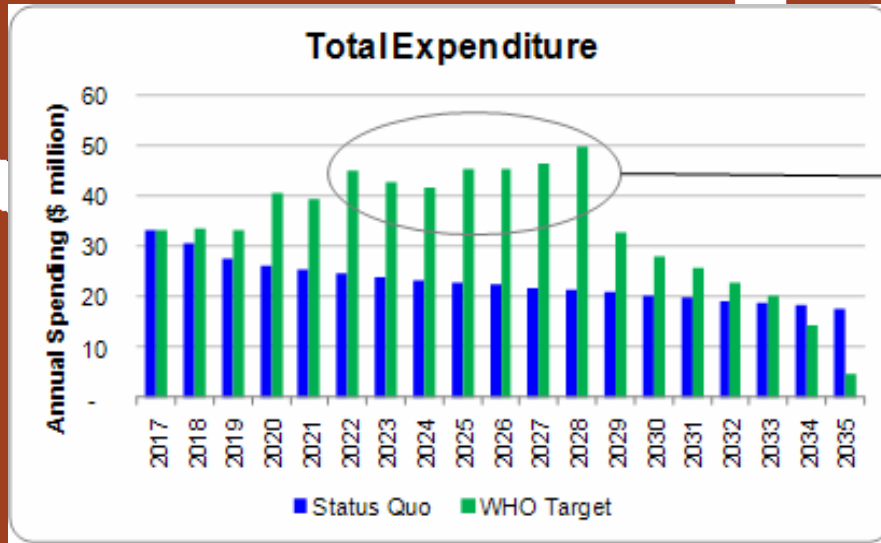
1. Healthcare systems who can afford to pay for the hepatitis elimination programs on their own – e.g., public health systems/ national governments (e.g., Viet Nam, Morocco...), private large employers (Heineken, Pepsi, oil companies...), medical missions, NGOs, aid groups, and service clubs (e.g., Rotary, Lions...).
2. Healthcare systems who can borrow money to support the hepatitis elimination programs – e.g., public health systems/ national governments (e.g., Egypt, Mongolia...).
3. Healthcare systems who cannot afford the upfront payment for an elimination program – e.g., public health systems/ national governments in most low and lower middle-income countries.

The focus of this presentation is the third segment.

Hepatitis elimination has a positive return on investment (ROI) – the big problem is the upfront investment



Healthcare expenditure in Cameroon under status quo and HCV elimination scenarios





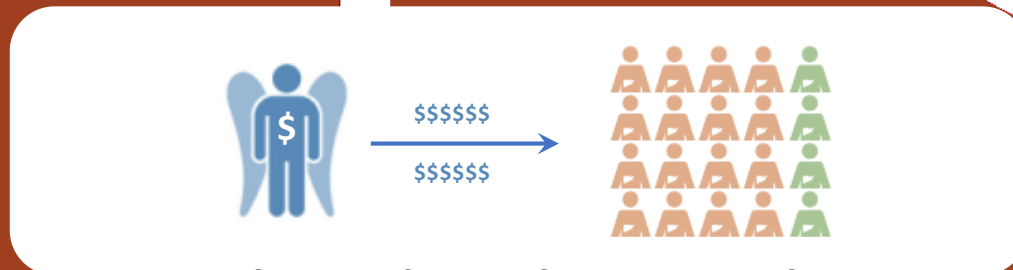
Key assumptions

- ✓ Patients are willing to, and do, pay for healthcare expenses in LMIC
- The majority of patients are able to pay for treatment & screening if the costs are kept below the catastrophic healthcare expenditure level
- ✓ Some portion of the population will not be able to pay for their healthcare
- ✓ The supply chains are inefficient and there are significant mark-ups before products reach the patients
- ✓ Exchange of payments provide opportunities for mark-ups
- ✓ Suppliers are willing to provide price concessions if large volumes are guaranteed
- The banks and donors would be willing to provide catalytic financing if they can get their investment back at the end of the program

The new model uses loans instead of donations to support the hepatitis elimination programs



Old Model – Donations Scale with Disease Prevalence



Donations from the few pay for the needs of the *many*, including for those who could afford some payment.


Patient who can Pay


Patient who can't Pay

Proposed Model – Patient Funds Scale with Disease Prevalence



Small **loan** from investor, plus funds from many patients, pay for diagnostics and treatment for all, plus repayment to investor.

Program Description



- All individuals receive screening for free (general population screening among adults)
- All who test positive for antibody receive confirmatory and RNA test (HCV) and HDV test (HBV) for free
- The patient payments (those who can pay) pays for the program
 - The cost to patients is kept below the catastrophic healthcare expenditure
- 20% of the patients (who can't afford) will receive treatment for free
- The loan is paid back at the end of the pre-agreed period

The current guidelines were not developed for an elimination program. For HBV, it is more efficient to treat everyone who is HBsAg positive (HDV negative) rather than testing them annually for disease progression.

The initiative takes a holistic approach to manage the final price to the patients



Low-Cost Procurement

- Pooled procurement of licensed generic Tx and quality-assured Dx at volume discount.



Deliver Affordable Interventions

- Screening is free for all
- Negotiated waiving of import duties and taxes, and negotiated pharmacy markups, to keep prices affordable.



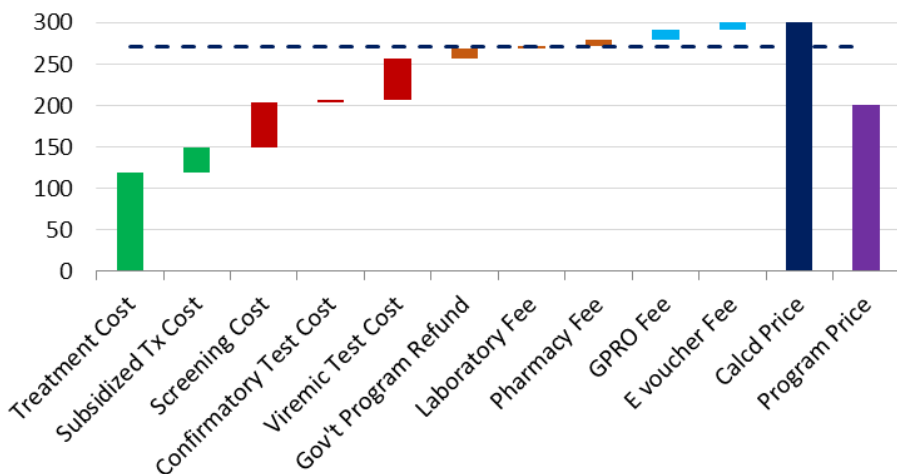
Enforce Negotiated Pharmacy Markups

- Utilize digital voucher technology, eliminating cash transactions and opportunistic pricing.

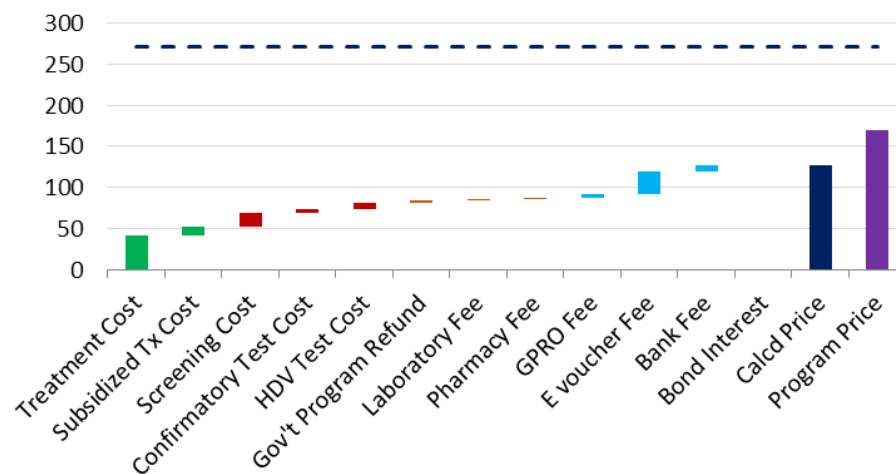
The waterfalls show how a portfolio approach can be used to manage costs across HCV and HBV – Universal Healthcare



HCV Price Waterfall (USD) - Nigeria



HBV Price Waterfall (USD) - Nigeria



Modest increase in patient-pay for a high prevalence disease can offset a significant reduction in patient-pay for a low prevalence disease.

These prices are significantly less than what the patients pay now.

Using a well designed screening program, the cost of screening & lab tests is \$2.0-3.0 per person screened



Check-In Station



HCV/HBV Rapid Test



Collect Contact Information



DBS for Confirmatory RNA Test



Lab Tests



- HCV confirmatory test
- HBsAg confirmatory test
- HCV RNA
- HDV



Summary

- We are looking to start a pilot program that screens 250,000 people and treat all who test positive for HCV & HBV (Nigeria, Ethiopia, Ghana, Cameroon, or Uzbekistan)
- This catalytic financing option is suitable for countries who can not afford to pay for their own hepatitis elimination program
- The financial requirement to implement the program is a loan rather than donations
- The program focuses on managing the mark-ups in the supply chain to minimize the cost to patients
- If successful, this model can be used to provide universal healthcare in the same countries – use a portfolio approach to manage cost to patients
- If successful, tiered pricing can be used to segment the patient population further

Questions & answers



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Session 4: Opportunities and challenges

Chairs:

Prof. Gamal Esmat, Cairo University

Prof. Dr. Charles Boucher, Erasmus University



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[@HepBCPPA](#)

Dr. Tatjana Reic

Chair of ACHIEVE Coalition



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INTRODUCING THE ACHIEVE COALITION

EU HCV POLICY SUMMIT, SESSION 4: OPPORTUNITIES AND CHALLENGES

Presentation by Tatjana Reic, Chair of the ACHIEVE coalition

ACHIEVE

ASSOCIATIONS COLLABORATING ON HEPATITIS TO
IMMUNIZE AND ELIMINATE THE VIRUSES IN EUROPE



LAUNCH EVENT, 7 JUNE 2017, EUROPEAN PARLIAMENT

ACHIEVE



ASSOCIATION COLLABORATING ON HEPATITIS TO IMMUNIZE AND ELIMINATE THE VIRUSES IN EUROPE

ACHIEVE COALITION

Our members

- European Liver Patients' Association
- Correlation Network
- World Hepatitis Alliance
- European AIDS Treatment Group
- Hepatitis B and C Public Policy Association
- IS Global
- Viral Hepatitis Prevention Board
- EASL International Liver Foundation



Supported by
Abbott, AbbVie, Cepheid, Gilead, MSD

Our mission

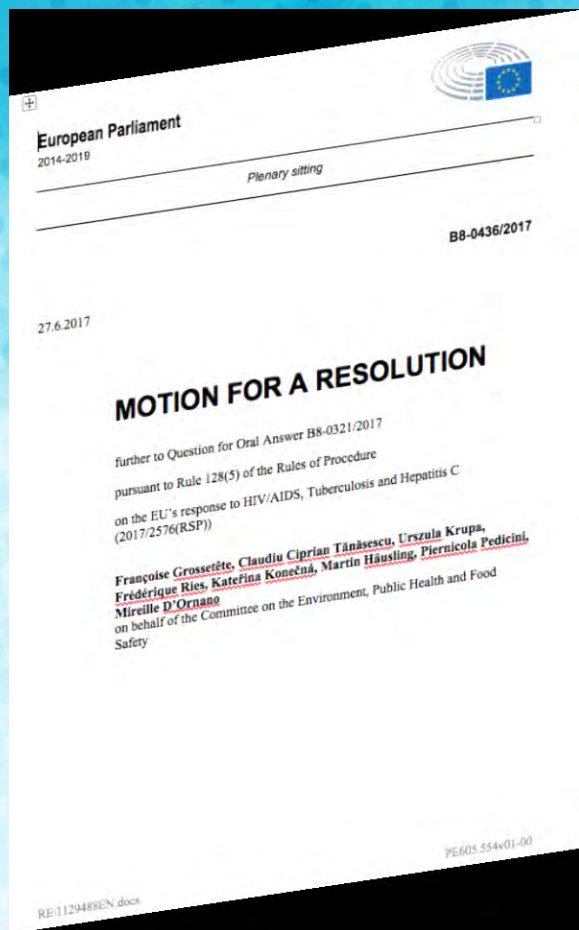
To advance the fight against viral hepatitis B and C in line with the WHO Global Health Sector Strategy, the WHO Europe Action Plan and the UN Sustainable Development Goals and achieve elimination by 2030.

POLICY GOALS

6 Areas of Action

1. EU GOVERNMENTS to reaffirm **elimination goal by 2030** and **make commitment** to its **implementation**.
2. Calibrate the **true scale** of viral hepatitis in Europe
3. Measure and **raise awareness of viral hepatitis** amongst the population.
4. Improve **diagnosis** in **primary care** settings.
5. Improve diagnosis and **access to guideline-conform treatment amongst defined key groups**, such as people who inject drugs (PWID), prisoners and specific groups of migrants, whilst addressing stigma.
6. Provide **sustainable, affordable, universal access** to the tools for elimination.

EUROPEAN PARLIAMENT RESOLUTION, JULY 2017



1. Monitoring

European Parliament Resolution on the EU's response to HIV/ AIDS, Tuberculosis and Hepatitis C, July 2017:

" Update of Dublin Declaration to put HIV, viral Hepatitis and TB on an equal footing"...

"EU-wide harmonised infection surveillance programme that can detect outbreaks of viral hepatitis, TB and HIV in a timely manner, assess trends I incidence, provide disease burden estimates and effectively track in real time the diagnosis, treatment and care cascade, including for specific vulnerable groups"

2. Screening

European Parliament Resolution on the EU's response to HIV/ AIDS, Tuberculosis and Hepatitis C: *"to best equip primary healthcare professionals (), with a view to increasing the diagnosis rate and ensuring guideline-conform care."*

3. Funding

European Parliament Resolution on the EU's response to HIV/ AIDS, Tuberculosis and Hepatitis C: *"to make use of EU Structural Funds and other available EU funding for national viral hepatitis elimination plans."*

ENCOURAGING POLICY DEVELOPMENTS

- EU Civil Society Forum now includes representatives of the viral hepatitis community
- In a written statement on World Hepatitis Day European Commissioner Vytenis Andriukaitis calls on readers to *"really work together so that ultimately we can stamp out this "silent" epidemic. Together we can eradicate Hepatitis in Europe."*
- ECDC-led work on developing effective indicators to monitor progress
- European Commission Staff Document on HIV/ Aids, Tuberculosis and viral Hepatitis to be published by July 2018



ACHIEVE-VHPB MEETING IN ROMANIA, 17 MAY 2018



Observations

- Monitoring along the cascade of care made difficult through insufficient linkages of data
- Close cooperation necessary between Ministries of Health and Finance
- EU Funding for Screening Programmes



ASSOCIATION COLLABORATING ON HEPATITIS TO IMMUNIZE AND ELIMINATE THE VIRUSES IN EUROPE

WHAT DO WE NEED TO DO TO NOW?

ACHIEVE

- Build on support of European Parliament to achieve traction
- Leverage messages from upcoming European Commission Staff Working Document in contacts with global, EU and national policymakers
- Influence the agenda of the next European Commission and the governments of EU Council Presidencies during the transition 2019-2020



- Only then, elimination by 2030 can become a reality.

Eberhard Schatz

**Coordinator, CORRELATION Network &
European Civil Society Forum**



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Challenges and Opportunities

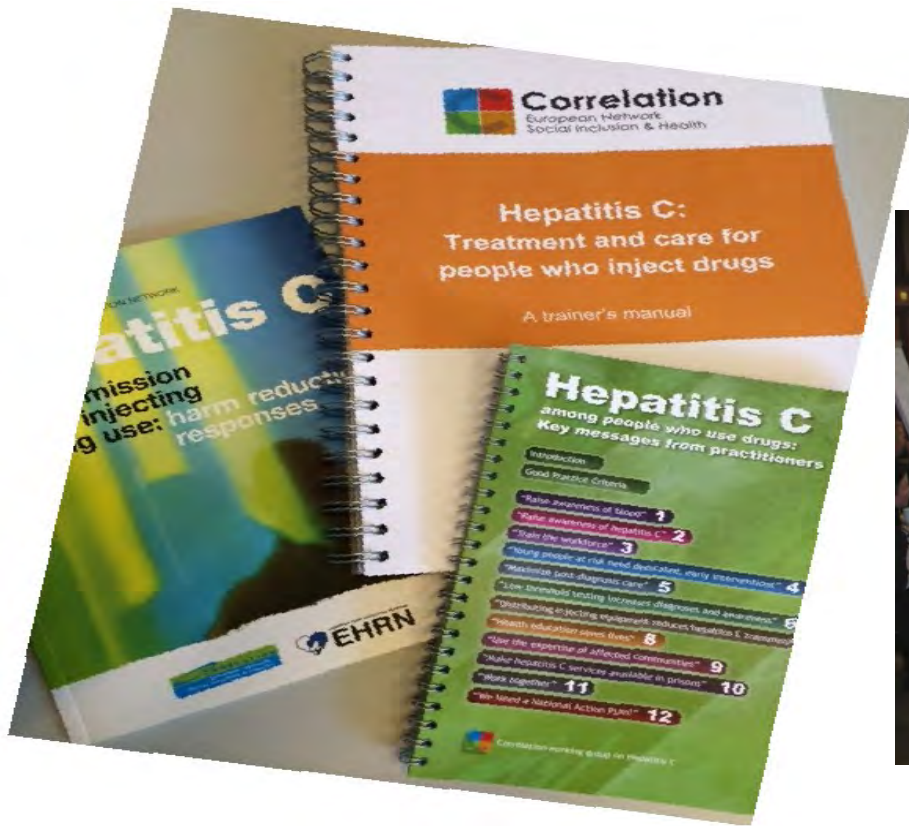
How to increase access to testing and treatment for PWID's



Correlation

European
Harm Reduction
Network

- **Improve access and quality of health and social services for marginalised groups**
- European network since 2004
- More than 220 partners in all European countries
- Hepatitis C Initiative since 2014
- Host of the International Network of Drug Consumption Rooms



Trainings

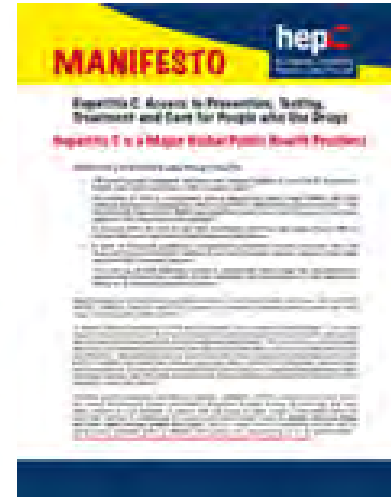
The two-day curriculum included:

- Prevalence of HCV in EU and locally
- The liver and hepatitis virus
- HCV testing and screening
- HCV rapid testing demonstrations HCV pre/post test counselling
- HCV prevention needs for drug users
- Injection techniques/demonstration
- Behaviour counselling/interventions
- Prevention planning demonstrations HCV services integration planning
- Anonymous training evaluation.



European Conference on Hepatitis C and Drug Use Berlin 23-24 October 2014

- 1
- 1
- 1
- 1
- 1
- 1
- 1



- Develop targeted HCV strategies and action plans
- Provide access to and affordability of HCV testing, treatment and care services
- Scale up evidence based harm reduction services
- Decriminalise people who use drugs
- Meaningful inclusion of PWID's
- Increase HCV and health literacy

HEPATITIS-C

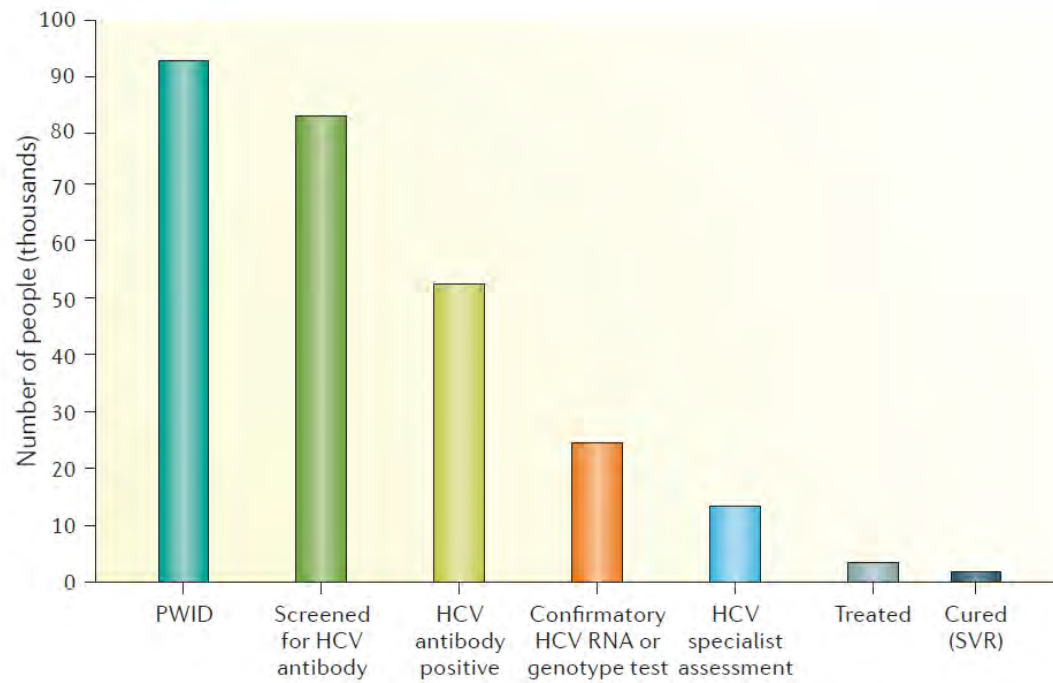
Community Summit

Amsterdam 18/19 April 2017

Challenge and Opportunity

Increase access to testing and treatment for PWID's

Cascade of Care?



Grebely J, Hajarizadeh B, and Dore GJ *Nat Rev in Gastroenterology & Hepatology* 2017. Iversen J, et al. *Int J Drug Pol* 2017.

Advances in diagnostics and point-of-care testing

Rapid diagnostic tests



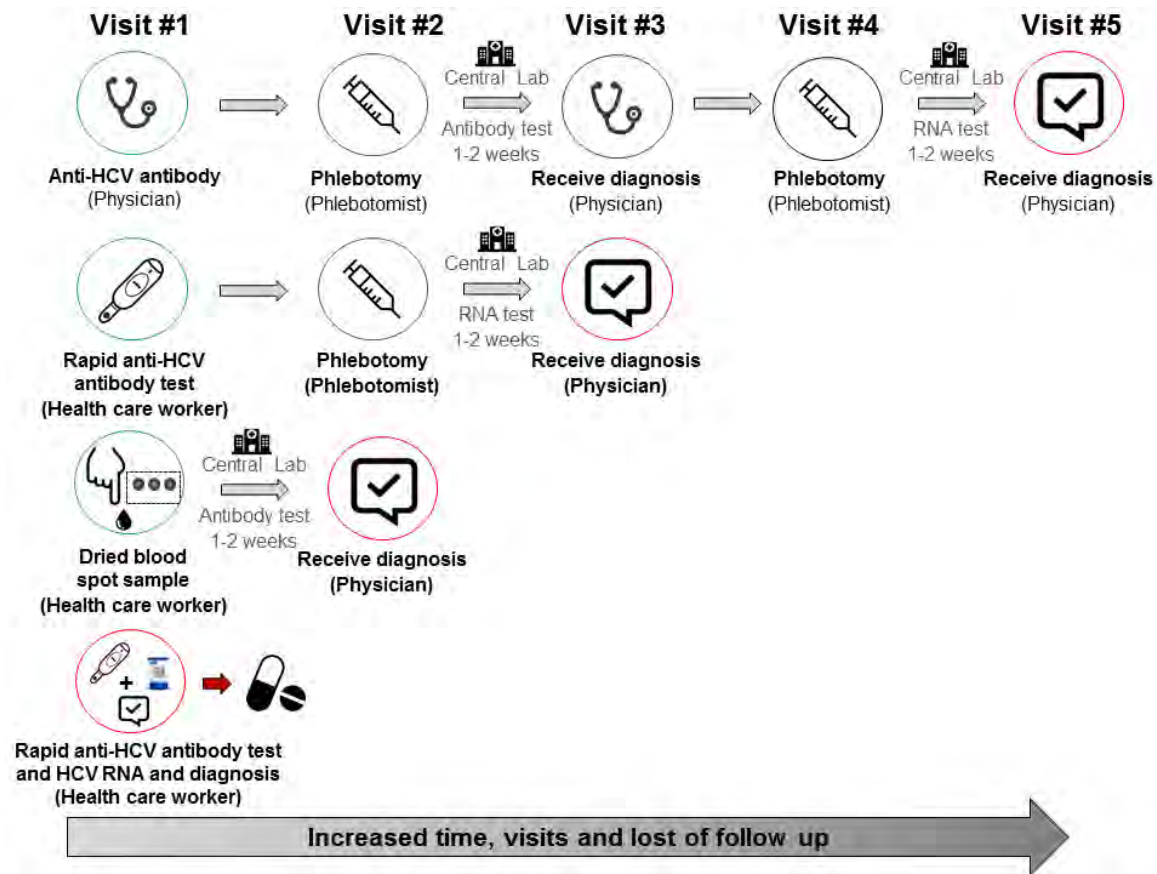
Dried blood spot testing



Point of care and random access HCV RNA testing



Moving to a single-visit hepatitis C diagnosis



Need to move towards simplified models of HCV care

- Many programs for HCV treatment are built upon interferon-era
- Need to move towards simplification of existing models



- Not at the expense of strengthening foundation for drug user health

The Role of Harm Reduction

- The new treatment options are easy to provide in community settings. Hospital attendance requirements are evidenced barriers for marginalized populations.
- Increase screening efforts in risk groups and build capacity for treatment
- Increase awareness and knowledge of HR workers
- Enable or increase community involvement
- Pro active linkage to health institutions
- Don' t forget about prevention as prevention



Challenge and Opportunity

Increase Funding For Harmreduction



HRI is campaigning to redirect just a tenth of the money spent in the war on drugs to harm reduction – 10 per cent by 2020.

10%
could...

Fill the gap in HIV
and Hepatitis C
prevention for
people who use
drugs twice over.

Strengthen networks
of people who use
drugs to provide peer
services and campaign
for their rights.

Roll out Naloxone,
enabling us to
prevent thousands
of overdose deaths
every year.



HEP-C

Community Summit
Lisbon 18 Sept 2018

Dr. Ricardo Baptista Leite

Member of Portuguese Parliament



#EliminateHCV
@HepBCPPA



Hepatitis C: Political Leadership for Elimination

Opportunities and Challenges

Brussels, 6th June 2018

Ricardo Baptista Leite, MD, MP

Medical Doctor and Member of the Portuguese Parliament

Member of the Parliamentary Health Committee | Foreign Affairs Committee

*Founder and President of 'UNITE – Parliamentarians Network to End HIV/AIDS,
Viral Hepatitis and other Infectious Diseases'*

Head of Public Health | Católica University of Portugal

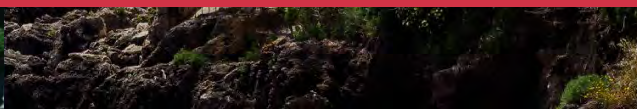
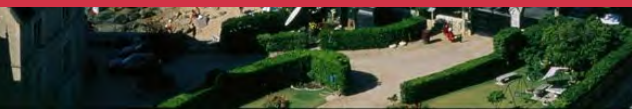
Guest Lecturer | NOVA Medical School

Guest Lecturer | NOVA Information Management School

ricardo.baptistaleite@gmail.com | @RBaptistaLeite



Portugal: Cascais – Sintra – Estoril Coast



HIV in Portugal

Number of New HIV Infections 1983-2016



1979

1983

1996 2000

2011



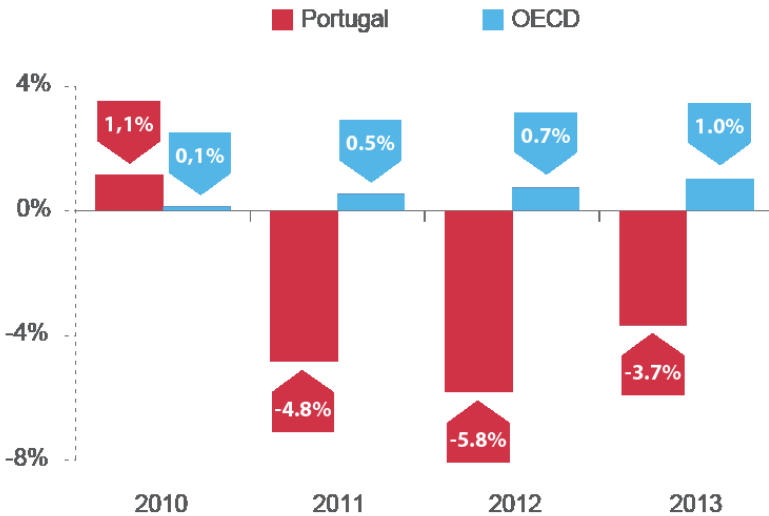
1st Dx HIV
in Portugal

HAART Drug Addiction as
Health Challenge

TROIKA

HIV in Portugal

2011 | TROIKA@Portugal



* Per capita spending in real terms.
Source: OECD Health Statistics 2015



HIV in Portugal

2011 | HIV Resolution



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HIV in Portugal

Number of New HIV Infections 1983-2016



1979

1983

1996 2000

2011 2015 2016

HEP C



1st Dx HIV
in Portugal

HAART

Drug Addiction as
Health Problem

TROIKA T&T

Fast Track Cities
PrEP

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Hepatitis C: Policy in Action

Hepatitis C in Portugal

Hepatitis C

STORY



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Hepatitis C: Policy in Action

HCV Paradigm Shift

2013 - 2014



Católica University of Portugal

Institute of Health Sciences
Public Health Unit



CATÓLICA
INSTITUTO DE CIÊNCIAS DA SAÚDE

LISBOA · PORTO · VISEU

Consensus Method[®]

Review scientific data

Collect data from main stakeholders (*Think Tank*)

Consensus paper to support future decisions on how to manage hepatitis C in Portugal, from a public policy perspective: *from prevention to cure*

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Hepatitis C: Policy in Action

HCV | The Research to Policy Gap



June -
December
2014

Only ~50 patients with Hepatitis C were treated with 3rd generation antiviral drugs (special authorizations)

Negotiations between Ministry of Health and Pharma Industry went on behind closed doors. **Absolute uncertainty on what would be the outcome of those negotiations.**

Private hospitals were charging over 100k Euros to treat Hepatitis C.

Advocats from all fields were demanding a decision, including a possible patent violation (under the Doha treaty), **to save lives.**

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Hepatitis C: Policy in Action

The Tipping Point

February 2015



Hepatitis C: Policy in Action

The Tipping Point

February 2015



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“DON'T LET ME DIE!”

José Carlos Saldanha

@RBaptistaLeite

Hepatitis C: Policy in Action

HCV | When Research meets Policy



February 2015



The Ministry of Health announced an agreement with Gilead Sciences and Harvoni® was fully funded for all patients with Hepatitis C.

Risk sharing model was adopted. The Ministry agreed on paying per patient that is clinically cured (not per number of weeks of treatment nor per number of patients treated) and the payment procedures were fully centralized.

Volume-based agreement: Price paid is inversely proportional to the number of patients treated.

National Action Plan for Hepatitis C and the review of the **national HCV treatment guidelines** were announced and are currently being prepared by a panel of experts.

Centralized registry database was commissioned and is currently used by physicians.

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Hepatitis C: Policy in Action

Hepatitis C in Portugal

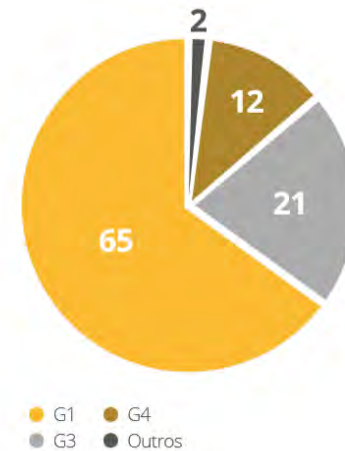
Today

Over 19.274 patients that have been diagnosed with chronic HCV in the NHS and their treatment has been authorized

17.432 patients have initiated treatment

9.897 PATIENTS CURED

96,6% SVR



Source: Ministry of Health PT, March 2018

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Hepatitis C: Policy in Action

Hepatitis C in Portugal

Health Outcomes

Feb 2015 – Feb 2017



Averted

3.477 premature
liver related deaths



Gained

62.869 life years



Averted

339 liver transplants,
1.951 liver cancers,
5.417 cases of chirosis



Savings

271.4 million Euros on
treatment costs related to
hepatitis c complications

Source: Martins J, Rodrigues J, Paula Martins A, Andreozzi V, Vandewalle B, Félix J, Castro Alves E, Mota-Filipe H. Long-Term Effect of the Portuguese Universal Access Program to New Generation Direct-Acting Antivirals for Treatment of Hepatitis C. EASL 2016, Barcelona, Poster #SAT-178.

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Hepatitis C: Policy in Action

Making Change Happen



2016 | Vienna, Austria

Policy change is possible using

EDD:

Evidence-based

Data-Driven

Decision-Oriented

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Give Politicians what they 'need'

Getting Political Leaders to push for Health Promotion

- In line with public concerns
- Clear 'Before and After' Data
- Savings, No or Low Cost (in this order)
- Timely results (*ie*, election period)



FUTURE: HEALTH PUBLIC POLICY TOOL



CATOLICA
INSTITUTO DE CIÊNCIAS DA SAÚDE
LISBOA-PORTO-VISEU

A digital tool that integrates the analysis of the history of disease, the treatment continuum, vulnerable populations and the impact of health policies



LETSENDHEPC.COM and download the APP 'LET'S END HEPC'

DECLARATION OF INTERESTS

Gilead Sciences Europe Ltd is providing financial support for this project.

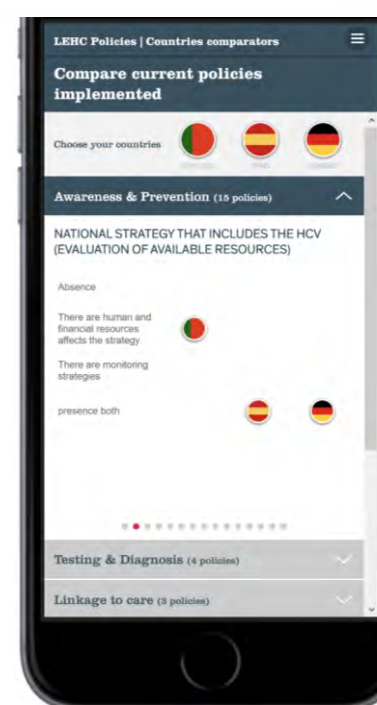
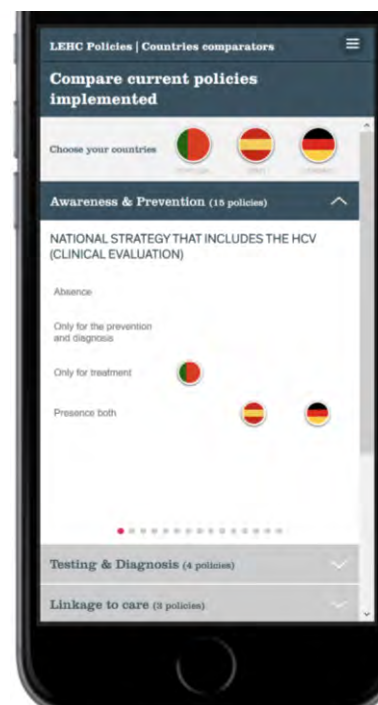
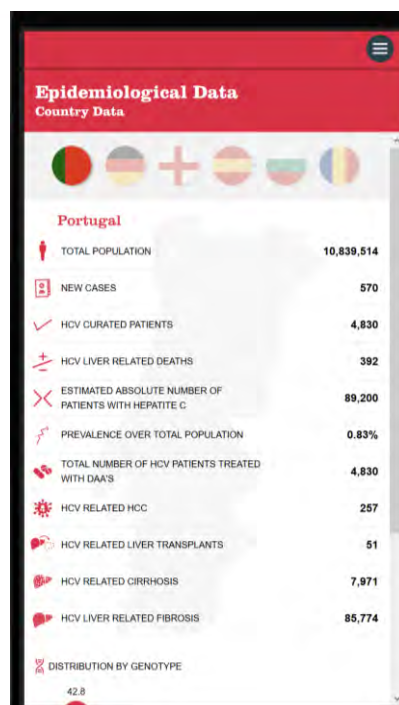
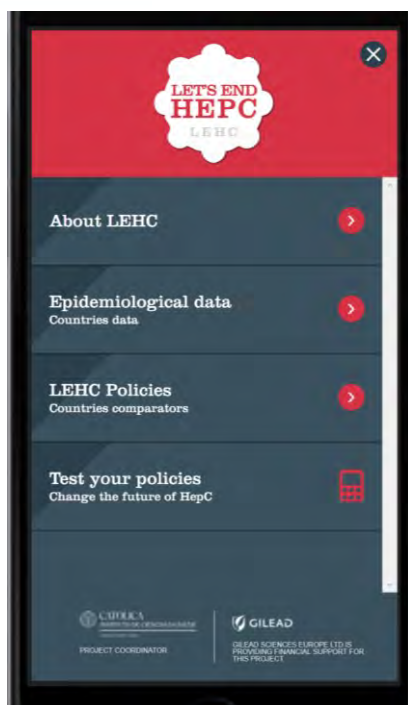
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FUTURE: HEALTH PUBLIC POLICY TOOL



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POLICY IMPACT ON HEALTH OUTCOMES

- Main HCV Outcomes
- Per Year 2019-2030
- Vulnerable Populations



Elimination of HCV will not be achieved by 2030 with current policies
(according to WHO elimination definition of HCV cut off of 90%).



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FUTURE: HEALTH PUBLIC POLICY TOOL



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POLICY CALCULATOR

*'Gamification of
Policy Making'*

LET'S END HEPC

About LEHC Epidemiological data LEHC Policies LEHC Supporting P

2024

945,152 TOTAL POPULATION

154 LINKED TO CARE

888 COMPENSATED

8 INCIDENCE

89 ON TREATMENT

365 HCV PREVALANCE

107 CURED

24 HEPATOCELLULAR CARCINOMA

246 DIAGNOSED

1 LIVER TRANSPLANT

30

Change your policies and see where you can make a difference!

(*) - currently implemented policies

- National strategy that includes the HCV (clinical evaluation)
- National strategy that includes the HCV (evaluation of available resources)
- National clinical guidelines for the diagnosis and treatment of HCV
- Involvement of civil society in defending the interests and rights of patients with HCV
- Events or awareness campaigns for HCV
- National Register of disease for HCV
- legal framework particularly in terms of discrimination of patients with HCV
- Involvement of primary health care
- national policy to address the prevention of HCV infection
- Screening for HCV in blood donations
- Screening for HCV in tissue and organ donations
- Measures "safe health" - screening and treatment of surgical instruments, equipment and supplies

LETSENDHEPC.COM
Download the APP
'LET'S END HEPC'

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FUTURE: HEALTH PUBLIC POLICY TOOL



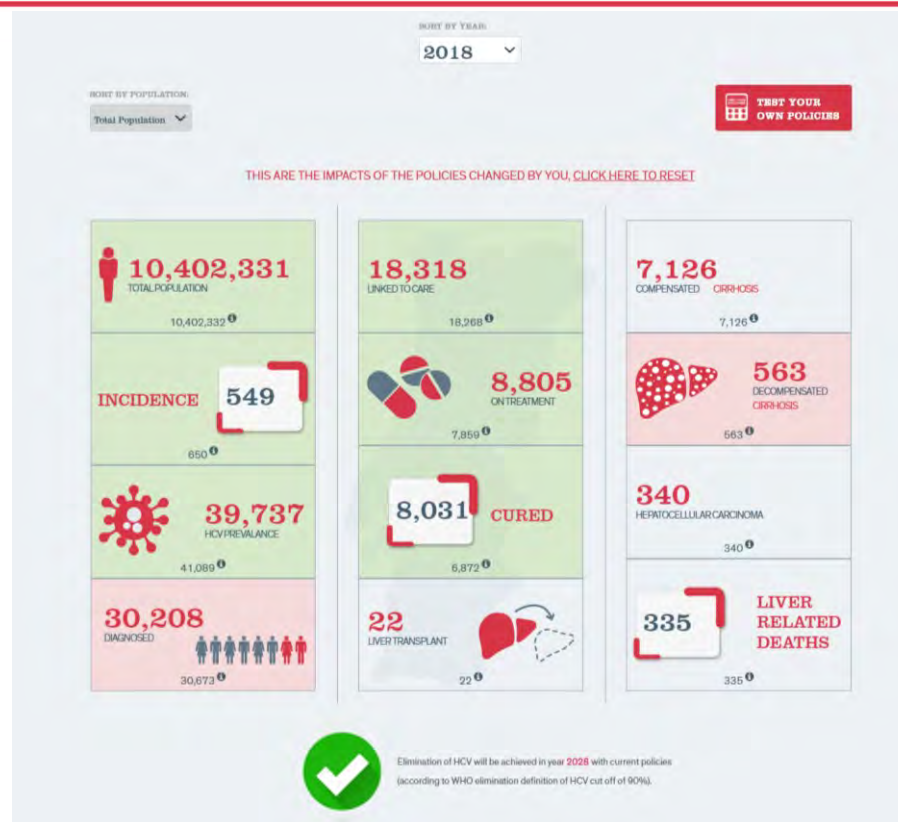
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POLICY CALCULATOR

*'Gamification of
Policy Making'*

LETSSENDHEPC.COM
Download the APP
'LET'S END HEP C'



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HCV in Portugal (and most European Countries)

What's missing to achieve Elimination?



- Action Plan with concrete indicators, goals and resources for the whole of the cascade
- Overcome the 'warehouse effect'
 - Ongoing awareness campaigns
 - Vulnerable populations | role of NGO's
 - General population | Digital reminders for GP's/ER's
- Ensure harm reduction services and systematic screening programs in prisons (and other settings) | Micro elimination starts with micro diagnosis

HCV in Portugal (and most European Countries)

What's missing to achieve Elimination?



- Integration of digital registry at point of diagnosis
- Digital and personal follow-up from diagnosis to treatment
- Include GP's as treatment prescribers

HCV in Portugal (and most European Countries)

What's missing to achieve Elimination?



- Advance towards *'Test & Treat'* (eliminating need for Linkage-2-care)
- Reassess need for all pre/post exams (fibrosan, HCV RNA,...)
- Facilitate access to treatment in all settings, including prisons and primary health clinics (and potentially testing sites)
- Include follow-up into the central registry

FALLING BEHIND



will·ing·ness

/'wiliŋGnəs/

noun

1. cheerfully consenting or ready:
2. Acting or ready to act gladly; eagerly compliant: a willing worker.
3. Done, given, or accepted voluntarily or ungrudgingly.



Taking action to deliver or global policy goals

Members of Parliament

- Approve national **budgets**
- Directly change local and national **policies**
- **Interface** between Governments and the People



Taking action to deliver on global policy goals

Still MP's are **excluded** from most International - Multilateral workgroups and decision processes



TAKING ACTION TO DELIVER ON GLOBAL POLICY GOALS

There is a need to foster an organized network of Parliamentarians to fight HIV/AIDS, Viral Hepatitis and other infectious diseases to:

Keep these diseases **high on the political and media agenda**

Address **life-long quality of life**, inequality, exclusion and changing epidemiological trends

Generate synergies in action by approaching these interrelated epidemics together in the context of the **Sustainable Development Goals (SDGs)**

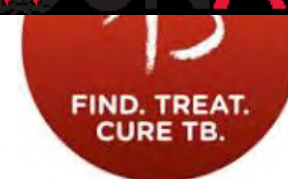
Focus responses and expand testing in **key populations**

Ensure **access** to treatment

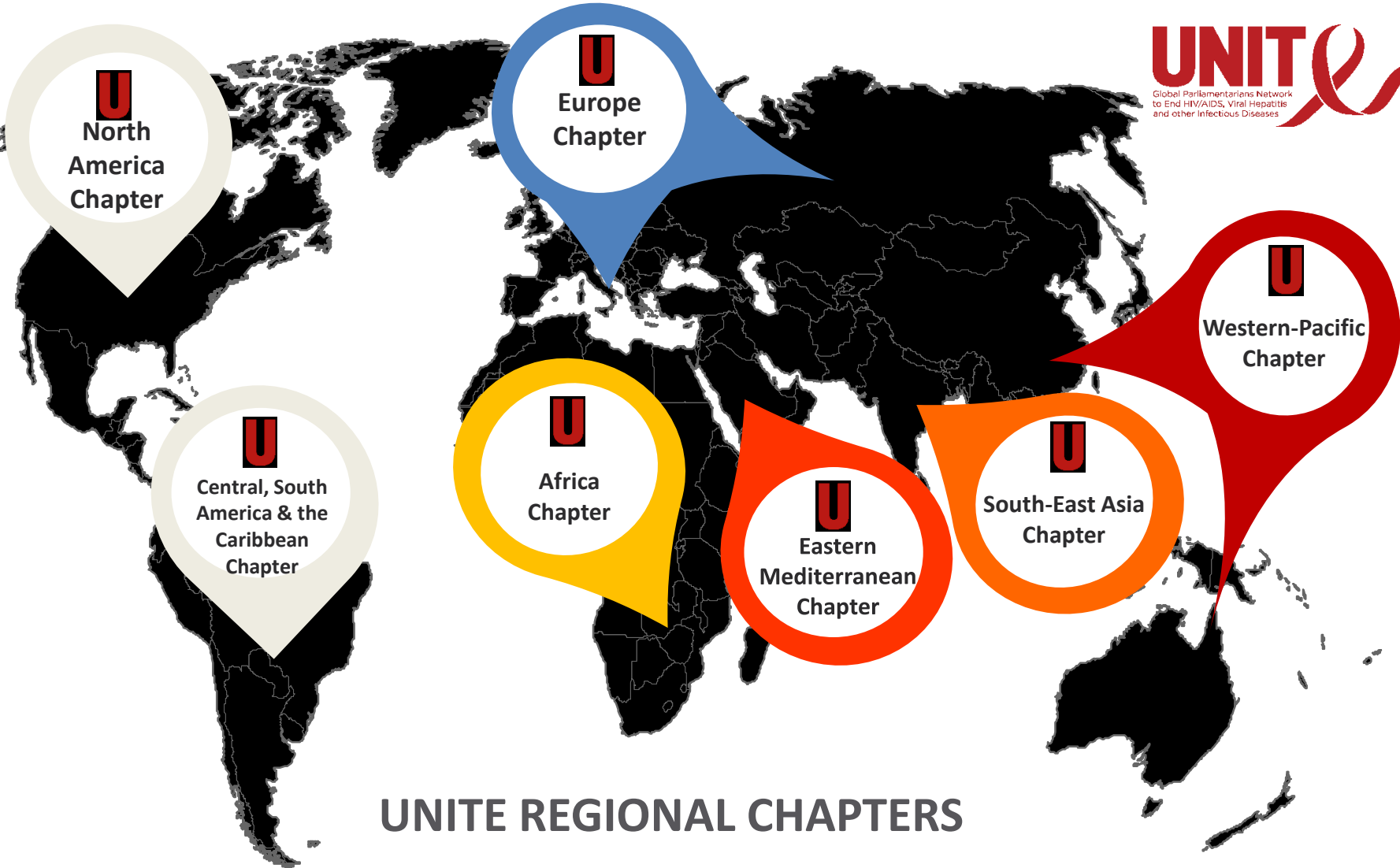
Promote **research & innovation**

UNITED
Global Parliamentarians Network
to End HIV/AIDS, Viral Hepatitis
and other Infectious Diseases

With the support and under the auspices of



@RBaptistaLeite



U
North
America
Chapter

U
Europe
Chapter

U
Western-Pacific
Chapter

U
Central, South
America & the
Caribbean
Chapter

U
Africa
Chapter

U
Eastern
Mediterranean
Chapter

U
South-East Asia
Chapter

UNITE REGIONAL CHAPTERS





It's time to REBOOT the political awareness and action towards ending HIV/AIDS, Viral Hepatitis and other Infectious Diseases

It's time to end HIV/AIDS,
Viral Hepatitis and other
Infectious Diseases.
It's time to **UNITE**.



www.unitenetwork.org

With the support and under the auspices of



Questions & answers



#EliminateHCV
@HepBCPPA

Next steps & invitation to Call to Action



#EliminateHCV
@HepBCPPA

Prof. Angelos Hatzakis

**Co-Chair, Hepatitis B&C Public Policy
Association**

Prof. Jeffrey Lazarus

**Associate Professor, University of Barcelona,
ISGlobal**



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2nd EU HCV Policy Summit

Securing sustainable funding for Hepatitis C Virus elimination plans

Endorsed by:



<http://www.hcvbrusselssummit.eu>



#EliminateHCV
@HepBCPPA

Call to Action

“Secure sustainable funding for viral hepatitis C elimination plans”

We, the signatories of the Call to Action “Secure sustainable funding for hepatitis C elimination plans” are committed to HCV elimination in Europe.

In line with the 2015 United Nations’ General Assembly Resolution “Transforming our world: the 2030 Agenda for Sustainable Development”, in line with the Sustainable Goal 3 Good Health and Well-Being and its Target 3.3 to Fight Communicable Diseases, in line with the 2014 World Health Assembly’s Resolution 67.6 on hepatitis, in line with the 2016 HCV Elimination Manifesto, in line with the WHO Global Health Sector Strategy on Viral Hepatitis 2016-2021 “Towards ending viral hepatitis”, and in order to encourage policy-makers to fulfil the Strategic Direction 4 of the WHO Global Health Sector Strategy on Viral Hepatitis 2016-2021, and make HCV elimination affordable, we are calling on the European decision makers to:



#EliminateHCV

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- 1) Ensure that countries have a comprehensive, costed hepatitis C elimination strategy in place, including a comprehensive monitoring along with the cascade of care in line with the criteria developed by ECDC and WHO Europe;



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- 2) Determine their country-level disease and economic burden of HCV by measuring direct and indirect socio-economic cost to improve the response towards HCV elimination, paying attention to the close link between HCV and HIV in some populations;



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- 3) Develop country and population-specific models, as viral hepatitis investment cases, to estimate lifetime costs, quality-adjusted life expectancy, and incremental cost-effectiveness ratios of different screening and treatment strategies with comparison with no action;



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- 4)** Allocate sufficient resources for training and research, developing robust models of care for tackling HCV, and urgently and effectively fulfil Strategic Directions 2, 4 and 5 of the WHO Global Health Sector Strategy;



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- 5) Recognise the need for the European Union to engage in HCV elimination by establishing a clear political road map and call for European financial institutions to raise public or private funding and use elimination programmes as a development tool;



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- 6) Encourage and engage all the stakeholders to collaborate in the development of innovative financing tools like social impact bond and others, with the aim of launching new social services and financing prevention services, including harm reduction, contributing to HCV elimination in a sustainable way;



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- 7) Exchange and implement best practices on funding healthcare and HCV elimination, including via micro-elimination approaches (8), at the national, regional and local levels to meet the WHO elimination goals by 2030 and preferably much earlier.



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**Thank you for your
attendance!**

**We invite you to sign the Call to Action on
hcvbrusselssummit.eu**



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