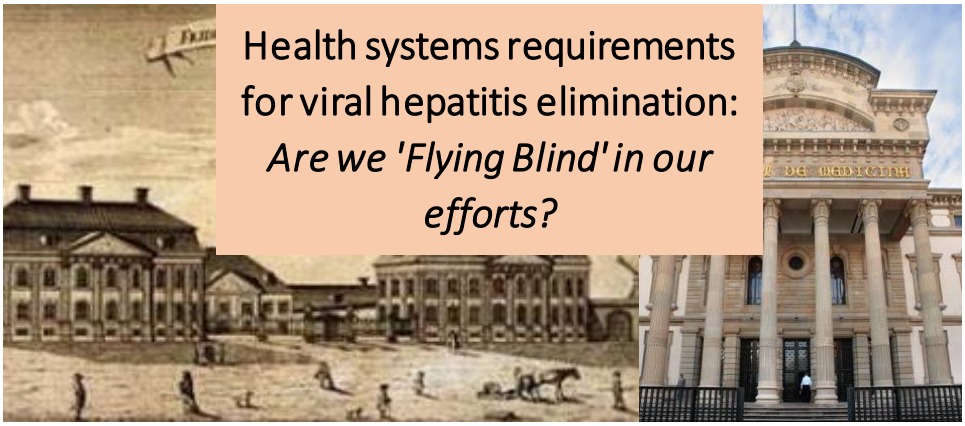


Health systems requirements for viral hepatitis elimination: *Are we 'Flying Blind' in our efforts?*

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

Associate Researcher, ISGlobal, Hospital Clínic, University of Barcelona

CHIP, Rigshospitalet, University of Copenhagen, WHO Collaborating Centre on HIV and Viral Hepatitis

Editor-in-Chief, *Hepatology, Medicine and Policy*

ISGlobal Barcelona Institute for Global Health | chip Centre of excellence for Health, Immunity and Infections | CLÍNIC BARCELONA Hospital Universitari | Rigshospitalet | HMAP Hepatology, Medicine and Policy

@JVLazarus - @immunization

Disclosures

- Grants and personal fees from AbbVie, 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

Some questions for you…

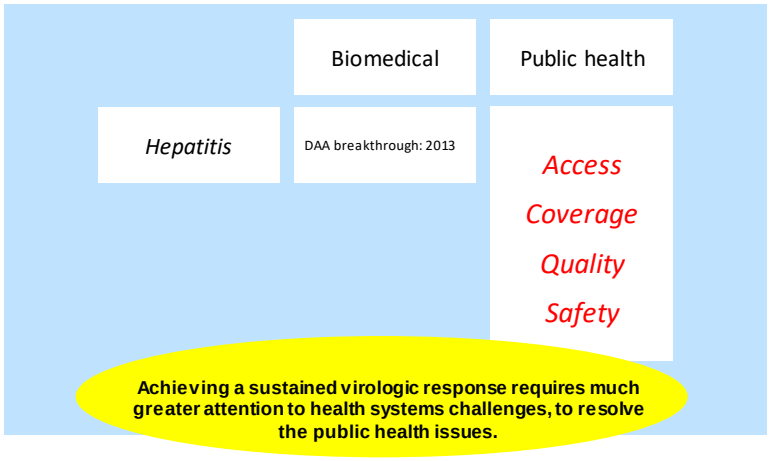
1. Do you believe that the global elimination of HCV as a major public health threat by 2030 is possible?
2. Are you familiar with the hepatitis elimination targets in the WHO GHSS on viral hepatitis?
3. Do the SDGs target viral hepatitis?

A question to ponder…

Translating good biomedical tools into good health outcomes for people living with hepatitis –

what will it take?

Meeting two types of challenges



But is it realistic to eliminate any infectious disease?

SMALLPOX IS THE ONLY HUMAN INFECTIOUS DISEASE TO BE ELIMINATED

BUT SMALLPOX WAS ELIMINATED THROUGH VACCINATION

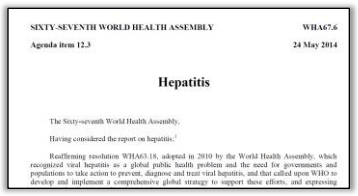
COULD HCV BE THE FIRST HUMAN INFECTIOUS DISEASE TO BE ELIMINATED THROUGH TREATMENT?

Source: Fenner F, *et al*. Smallpox and its Eradication. Geneva: World Health Organization 1988.

New global political will to eliminate HCV

First World Hepatitis Summit (2015)
84 countries represented

Hepatitis C Elimination in Europe (2016)
'Our vision for a Hepatitis C-free Europe'



SIXTY-SEVENTH WORLD HEALTH ASSEMBLY — WHA67.6
Agenda item 12.3 — 24 May 2014

Hepatitis

The Sixty-seventh World Health Assembly,

Having considered the report on hepatitis;[1]

Reaffirming resolution WHA63.18, adopted in 2010 by the World Health Assembly, which recognized viral hepatitis as a global public health problem and the need for governments and populations to take action to prevent, diagnose and treat viral hepatitis, and that called upon WHO to develop and implement a comprehensive global strategy to support these efforts, and expressing

EASL ENDORSED EVENT
EATG European AIDS Treatment Group
Hepatitis B and C Public Policy Association
ELPA
Correlation European Network Social Inclusion & Health
World Hepatitis Alliance
VHPB

Sources: World Hepatitis Summit 2015 meeting report. Available at: http://www.worldhepatitisalliance.org/sites/default/files/resources/documents/World%20Hepatitis%20Summit%20Report.pdf; Elimination manifesto. Available at: http://www.hcvbrusselssummit.eu/elimination-manifesto (both accessed January 2017)

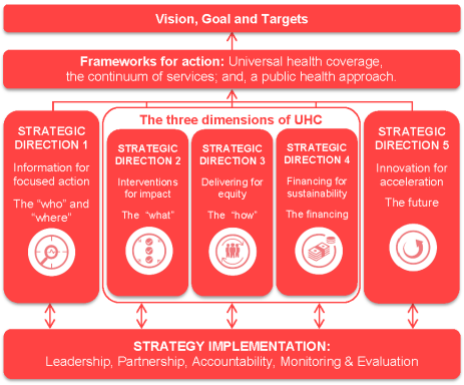
WHO Global Health Sector Strategy on Viral Hepatitis 2016–2021

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 on Viral Hepatitis, 2016-2021

- The five strategic directions of the Global health sector strategy on viral hepatitis, 2016–2021
- Governments/ regions need to address these in their national context



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

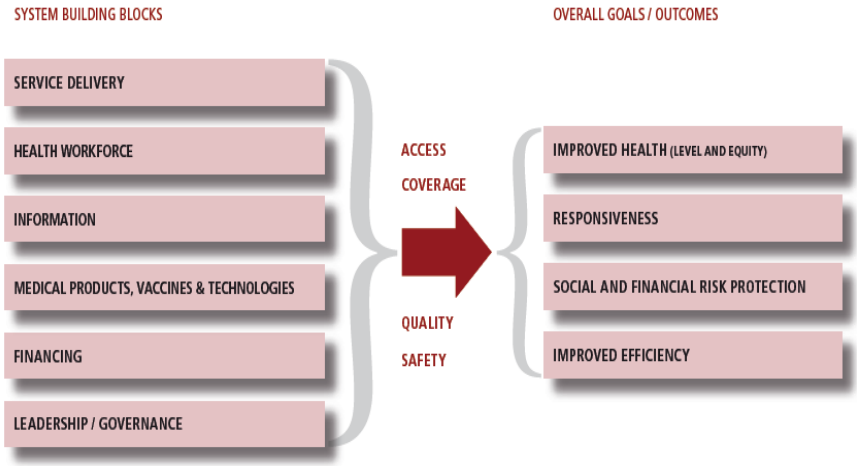
Harm reduction
- Increase in sterile needle and syringes provided per PWID/year from 20 in 2015 to:
  - 200 by 2020
  - 300 by 2030

Testing targets
- 90% of people aware of HCV infection by 2030

Treatment targets
- 80% of people treated by 2030

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

The Six Building Blocks of the Health System

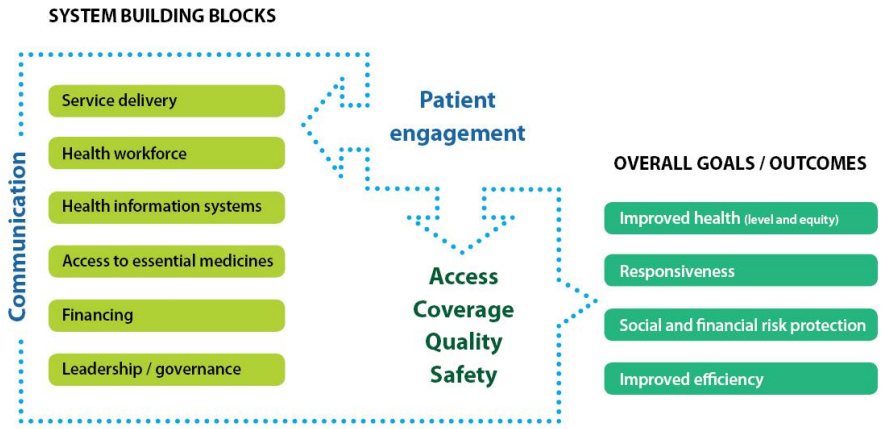


"A health system consists of all organisations, people and actions whose *primary intent* is to promote, restore or maintain health"

Source: WHO 2007.

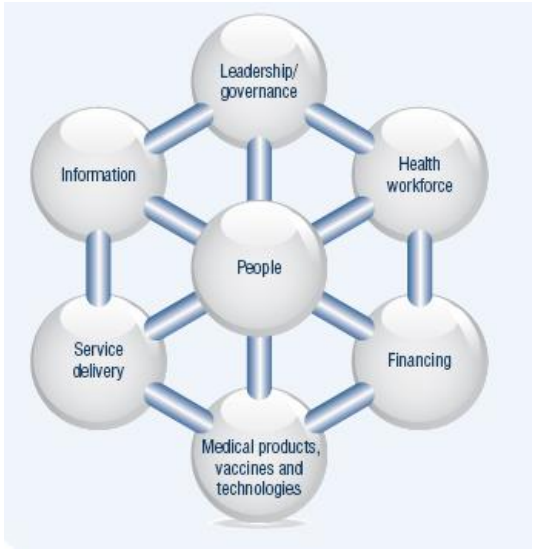
12

A paradigm change:
The central role of people and communication



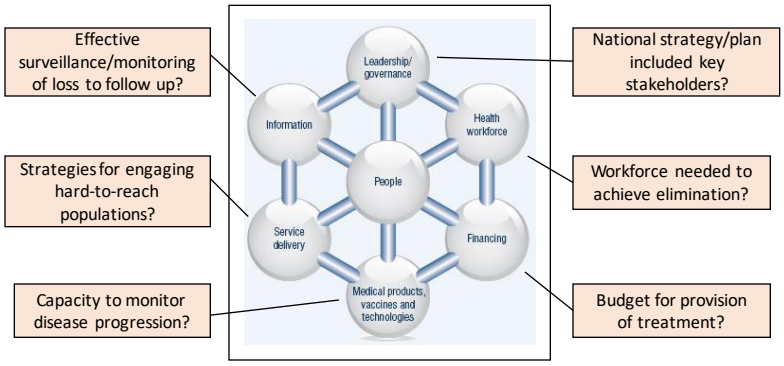
Source: Lazarus and France. A new era for the WHO health system building blocks? 2014

People-centred health systems



See: http://www.who.int/servicedeliverysafety/areas/people-centred-care/en/

A people-centred health system for hepatitis elimination



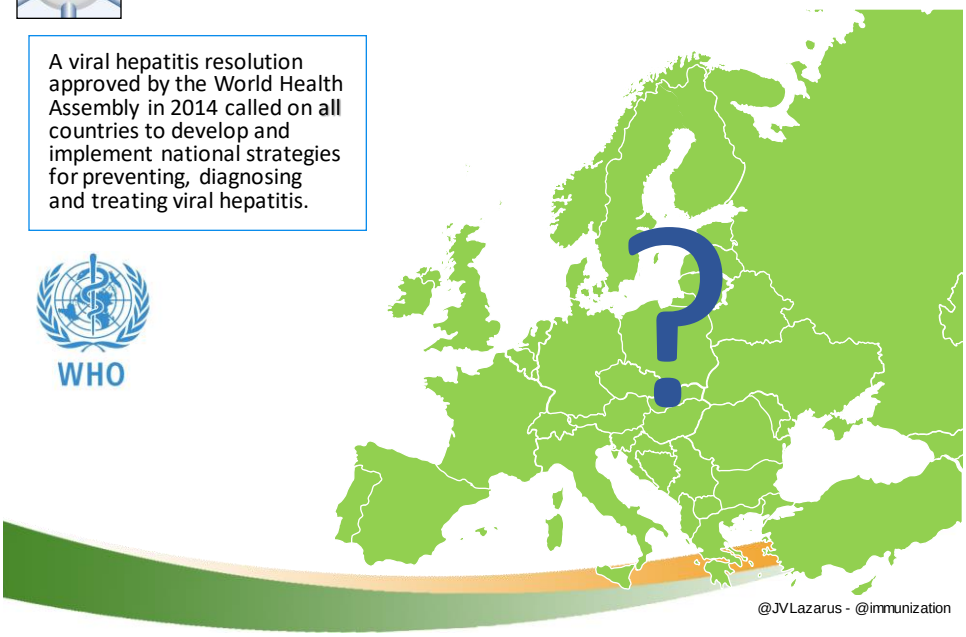
15 - #AVHEC17

@JVLazarus - @immunization

Eliminating HCV requires national plans

A viral hepatitis resolution approved by the World Health Assembly in 2014 called on all countries to develop and implement national strategies for preventing, diagnosing and treating viral hepatitis.

WHO



@JVLazarus - @immunization

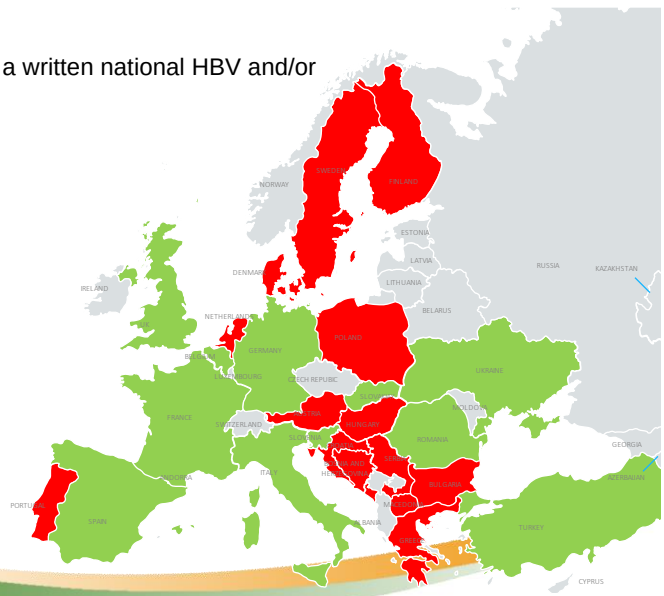
Many countries have developed national hepatitis plans

@JVLazarus - @immunization

National HCV strategy

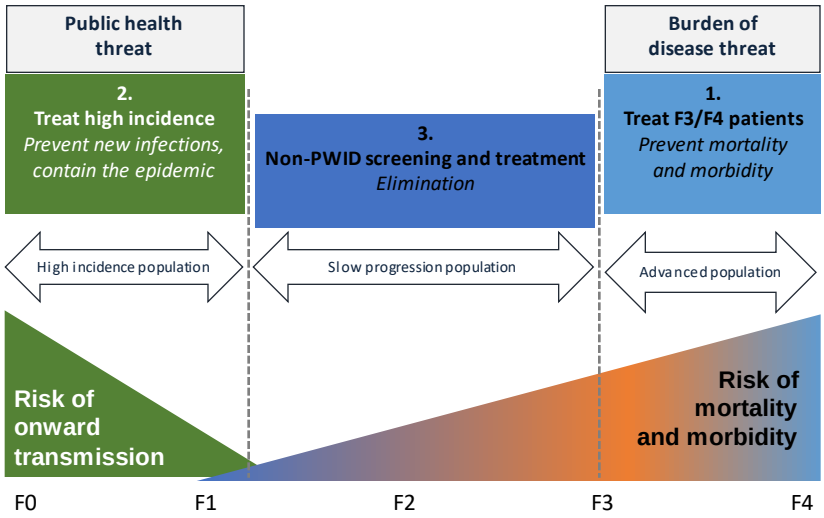
Does your country have a written national HBV and/or HCV strategy?

- Yes = 11
- No = 14
- Unknown / Unavailable



@JVLazarus - @immunization

Every country needs a bespoke strategy to reduce disease burden and eliminate HCV



⇨ One approach does not fit all – Context matters!

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

Decompensated cirrhotics

Veterans

Patients with haemophilia

Transplant patients

HIV/HCV co-infected

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

Expanding prescriber base

- In countries without prescriber restrictions, such as Australia, general practitioners and non-specialists have greater access to reach patients in need of treatment
- 5-15% of individuals initiating DAAs had treatment prescribed by a GP

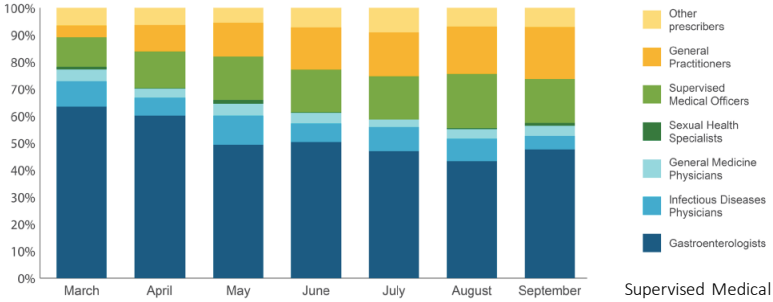
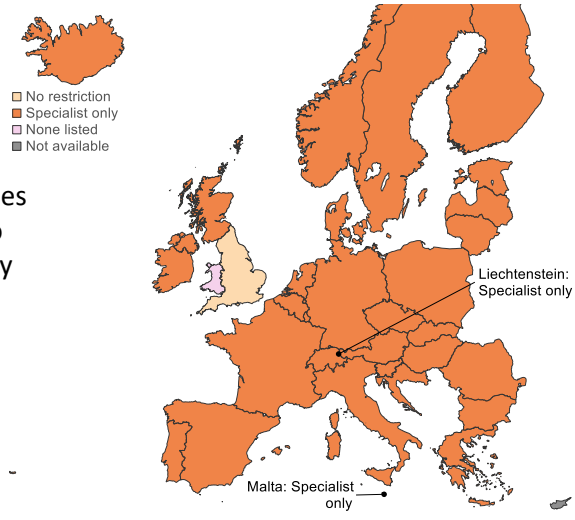


Figure 5: Prescriber distribution in each month for individuals initiating DAA treatment during March to September 2016 in Australia

Supervised Medical Officers included interns, temporary resident doctors, and non-vocationally registered doctors

Source: Hajarizadeh B, Grebely J, Matthews GV, Martinello M, Dore GJ. The path towards hepatitis C elimination in Australia following universal access to interferon-free treatments. Poster to be presented at: International Liver Congress. 2017; Amsterdam, Netherlands.

Specialist restrictions for DAA prescription

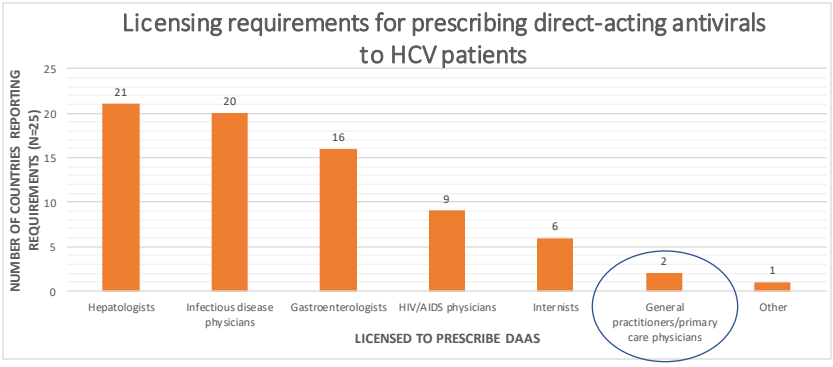


94% (n=32) of countries required specialists to prescribe DAA therapy

Hep-CORE

Licensing requirements for DAA prescription

- 24% (n=25) of patient groups surveyed reported that non-specialists are able to prescribe DAAs to HCV patients in their country and in only two cases were they GPs
- The majority (64%) require at least a gastroenterologist

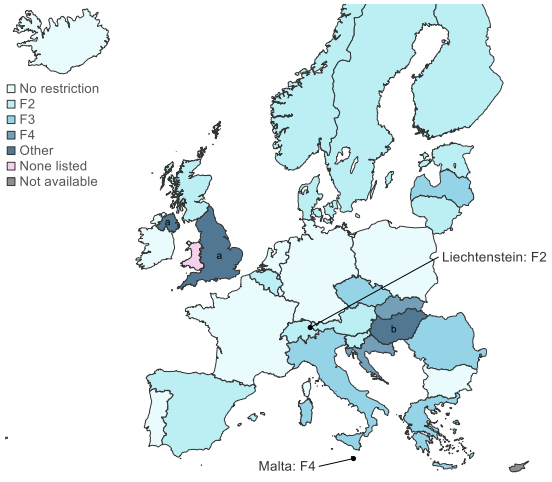


Source: The 2016 Hep-CORE Report: http://www.elpa.eu/sites/default/files/documents/Hep-CORE_full_report_21Dec2016_Final%5B2%5D.pdf

Minimum fibrosis stage required for DAA reimbursement

INHSU

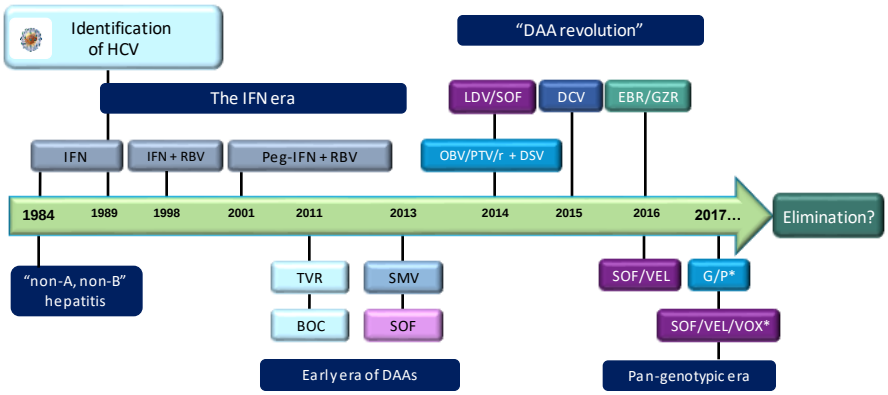
62% (n=21) of countries required evidence of ≥F2



[a] Fibrosis stage restrictions based on HCV genotype
[b] Fibrosis stage is included in a point system for prioritisation of DAA therapy

Source: Marshall, AD et al. Restrictions for reimbursement of interferon-free direct acting antiviral therapies for HCV infection in Europe. Poster presented at The International Liver Congress. 19-23 April 2017. Amsterdam, The Netherlands.

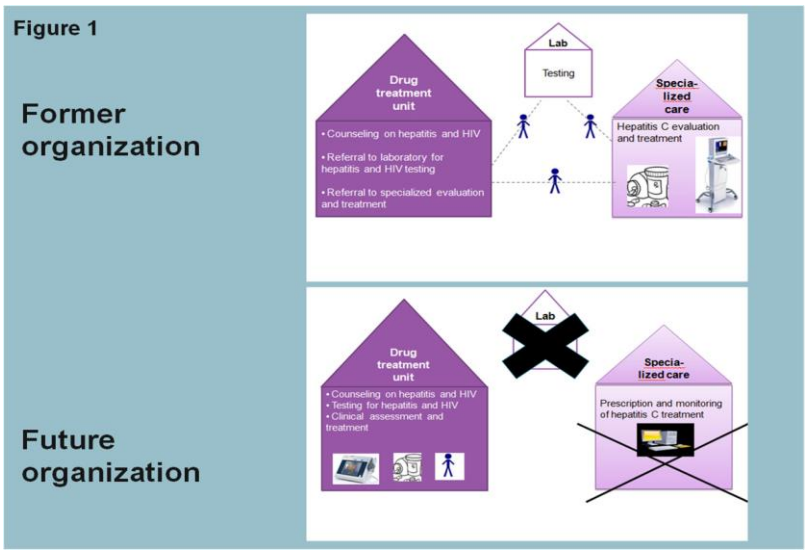
HCV Timeline: 1984-2017



* Regimen recently approved

Sources: Pawlotsky JM, *et al. J Hepatol* 2016; **62**: S87–99; Manns M, *et al. Nat Rev Dis Primers* 2017;**3**:1–19.

SACC: "Borgernær" shared care



Source: http://www.chip.dk/Collaborations/SACC

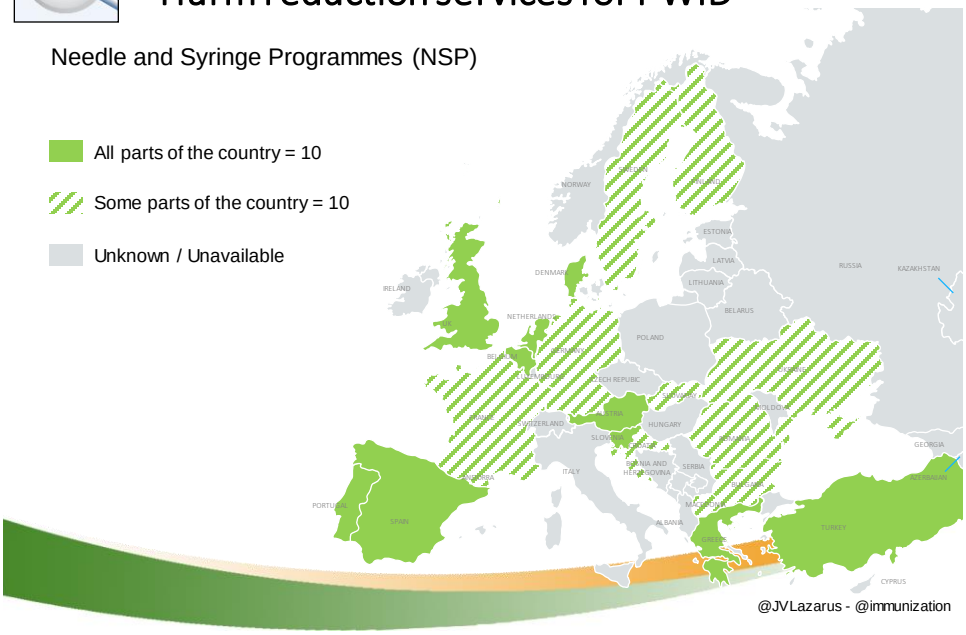
Harm reduction services for PWID

Needle and Syringe Programmes (NSP)

All parts of the country = 10

Some parts of the country = 10

Unknown / Unavailable



@JVLazarus - @immunization

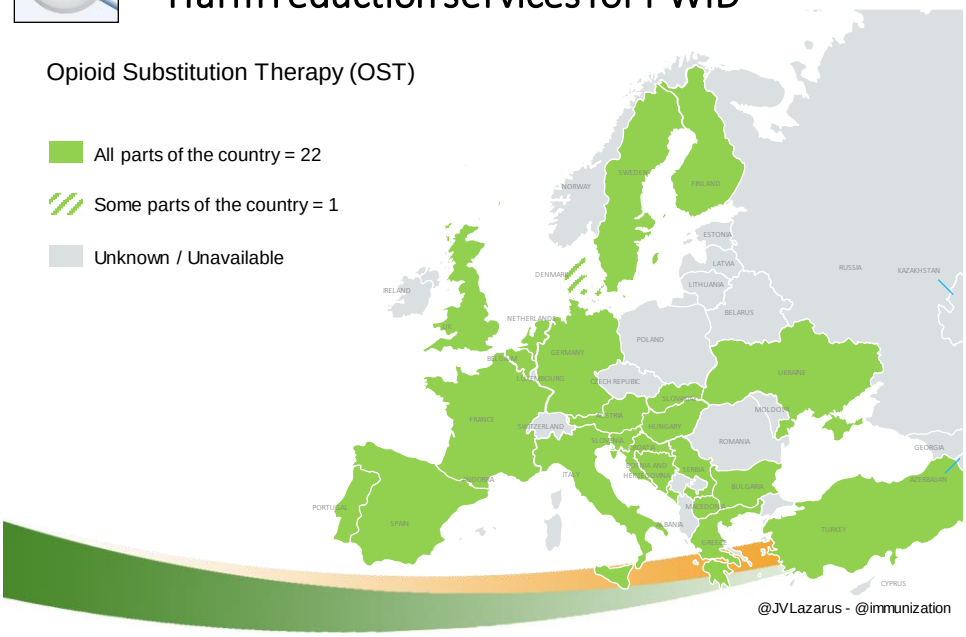
Harm reduction services for PWID

Opioid Substitution Therapy (OST)

All parts of the country = 22

Some parts of the country = 1

Unknown / Unavailable

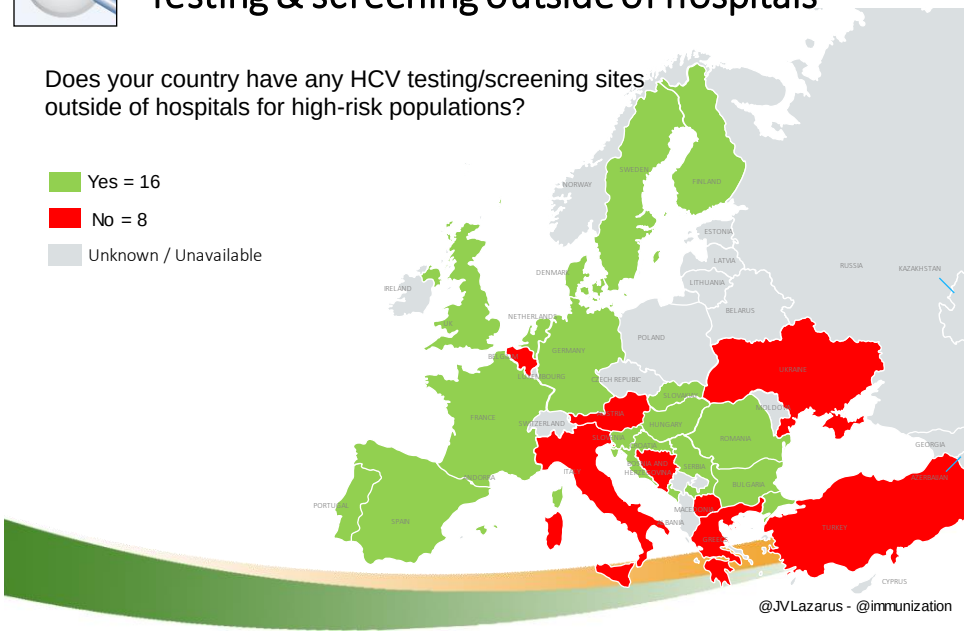


@JVLazarus - @immunization

Testing & screening outside of hospitals

Does your country have any HCV testing/screening sites outside of hospitals for high-risk populations?

- Yes = 16
- No = 8
- Unknown / Unavailable



@JVLazarus - @immunization

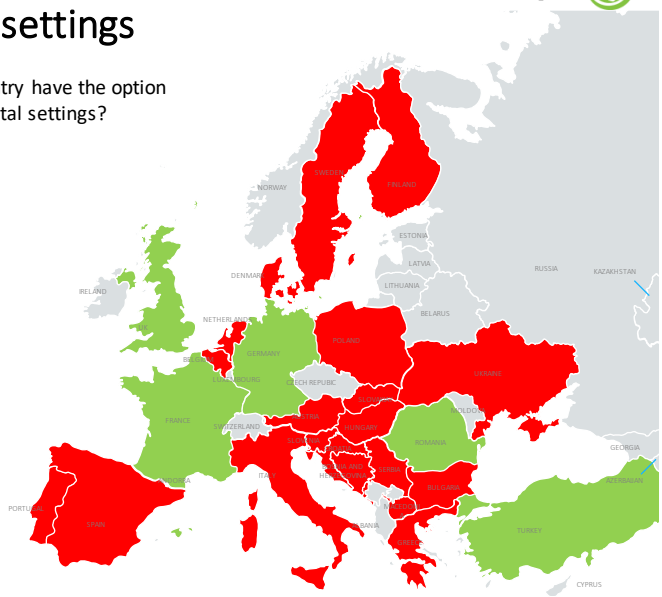
Treatment of HCV patients in non-hospital settings

Hep-CORE

Do HCV patients in your country have the option of being treated in non-hospital settings?

- Yes =5
- No =20
- Unknown / Unavailable

80% (n=25) of patient groups surveyed reported that HCV treatment is not available outside of a hospital setting



@JVLazarus - @immunization

Available HCV treatment in prisons

Hep-CORE

Is HCV treatment provided in prisons in your country?

Yes

No

Unknown / Unavailable

68% (n=25) of patient groups surveyed reported that HCV treatment is not available in prisons

Percentage of prisons providing HCV treatment:

AT: 10-19%

DK: 40-49%

FR: 0-9%

DE: 0-9%

HU: 20-29%

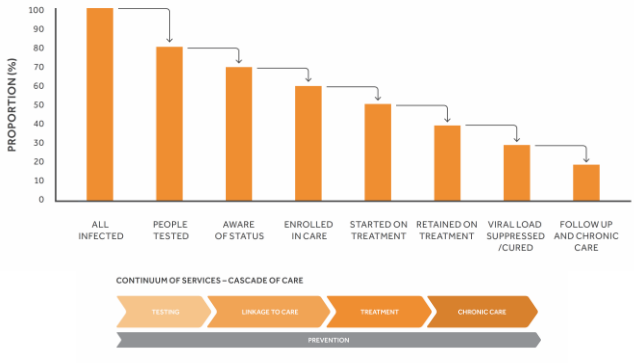
PT: 0-9%

SK: 100%

SV: 100%

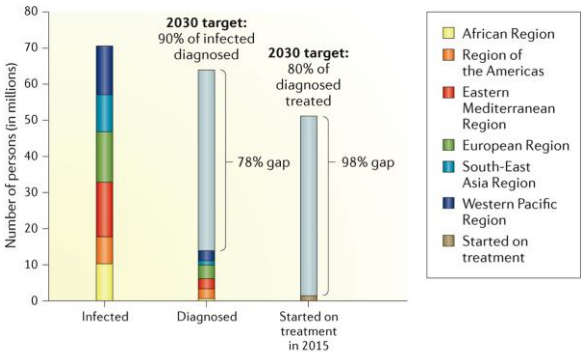
All other countries responding affirmatively were unable to specify percentages of prisons.

The continuum of viral hepatitis services and the retention cascade



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

The global cascade of care for chronic HCV infection in 2015



Nature Reviews | Gastroenterology & Hepatology

Adapted by Macmillan Publishers Ltd, part of Springer Nature with permission, from *Global Hepatitis Report, 2017*, World Health Organization, page 30, figure 8, 2017.

Source: Lazarus JV. *et al.* Many European countries 'flying blind' in their efforts to eliminate viral hepatitis. *Nat. Rev. Gastroenterol. Hepatol.* doi:10.1038/nrgastro.2017.98

Eliminate late presentation

Mauss *et al. BMC Medicine* (2017) 15:92
DOI 10.1186/s12916-017-0856-y

BMC Medicine

CORRESPONDENCE Open Access

Late presentation of chronic viral hepatitis for medical care: a consensus definition

Stefan Mauss[1,2], Stanislas Pol[2,9], Maria Buti[2,3], Erika Duffell[4], Charles Gore[5], Jeffrey V. Lazarus[6], Hilje Logtenberg-van der Grient[7], Jens Lundgren[6], Antons Mozalevskis[6,8], Dorthe Raben[6,10*], Eberhard Schatz[11], Stefan Wiktor[12], Jürgen K. Rockstroh[10,13] and on behalf of the European consensus working group on late presentation for Viral Hepatitis Care

Abstract

Introduction: We present two consensus definitions of advanced and late stage liver disease being used as epidemiological tools. These definitions can be applied to assess the morbidity caused by liver diseases in different health care systems. We focus is on hepatitis B and C virus infections, because effective and well tolerated treatments for both of these infections have greatly improved our ability to successfully treat and prevent advanced and late stage disease, especially if diagnosed early. A consensus definition of late presentation with viral hepatitis is important to create a homogenous, easy-to-use reference for public health authorities in Europe and elsewhere to better assess the clinical situation on a population basis.

Methods: A working group including viral hepatitis experts from the European Association for the Study of the

Some countries may achieve the WHO targets by or even before 2030

National plan to treat all HCV patients according to Icelandic guidelines over 3 years

- Prioritisation of active PWID and patients with moderate-to-severe fibrosis
- Jan to Dec 2016, 1/3 of the HCV population were treated

Georgia HCV Elimination Program

- Prioritisation of patients with advanced liver disease
- April 2015 to April 2016, 8448 people treated, a 400% increase in the number patients treated over the previous 4 years

Public health policy

- Access for all to highly effective HCV treatment was made a priority
- 2016, 15% (33,560 patients) of the HCV population were treated

Sources: Gottfredsson F, et al. HIV and Hepatitis Nordic Conference 2016; Abstract #O5;Gvinjilia L, et al. MMWR 2016;65:1132–5; Monitoring hepatitis C treatment uptake in Australia. Issue #5, September 2016. Available at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-7-july-2017 (accessed Aug 2017)

Putting it all together …

A people-centred health systems approach to HCV elimination in Australia

When we look at eliminating HCV as a public health challenge that should be approached from a health systems perspective …

What contributions to this historical moment do you see yourself making?

Acknowledgements

All authors of all cited studies in particular: Alison Marshall, Jason Grebely, Stine Nielsen, Evan Cunningham

and at ISGlobal, Barcelona: Samya R. Stumo, Kelly Safreed-Harmon

Get a koala for KV's birthday after conference

Contact: Jeffrey.Lazarus@isglobal.org

Hep-CORE study countries / ELPA members

Austria	Germany	Serbia
Belgium	Greece	Slovakia
Bosnia & Herzegovina	Hungary	Slovenia
Bulgaria	Israel	Spain
Croatia	Italy	Sweden
Denmark	Macedonia	Turkey
Egypt	Netherlands	Ukraine
Finland	Poland	United Kingdom
France	Portugal	
	Romania	

Hep-CORE study group

Charles Gore (World Hepatitis Alliance)
Hande Harmanci (WHO)
Magdalena Harris (LSHTM)
Greet Hendrickx (Viral Hepatitis Prevention Board)
Marie Jauffret-Roustide (Paris Descartes University)
Achim Kautz (ELPA)
Mojca Matičič (University Medical Centre Ljubljana)
Luís Mendão (Grupo de Ativistas em Tratamentos (GAT))
Antons Mozalevskis (WHO Euro)
Raquel Peck (World Hepatitis Alliance)
Tatjana Reic (ELPA)
Eberhard Schatz (Correlation Network)
Kaarlo Simojoki (A-Clinic Foundation, Finland)
Joan Tallada (European AIDS Treatment Group)

Hep-CORE funding to ELPA provided by AbbVie, Gilead Sciences, MSD.