HCV Treatment as Prevention (TAP) in risk groups:

An overview

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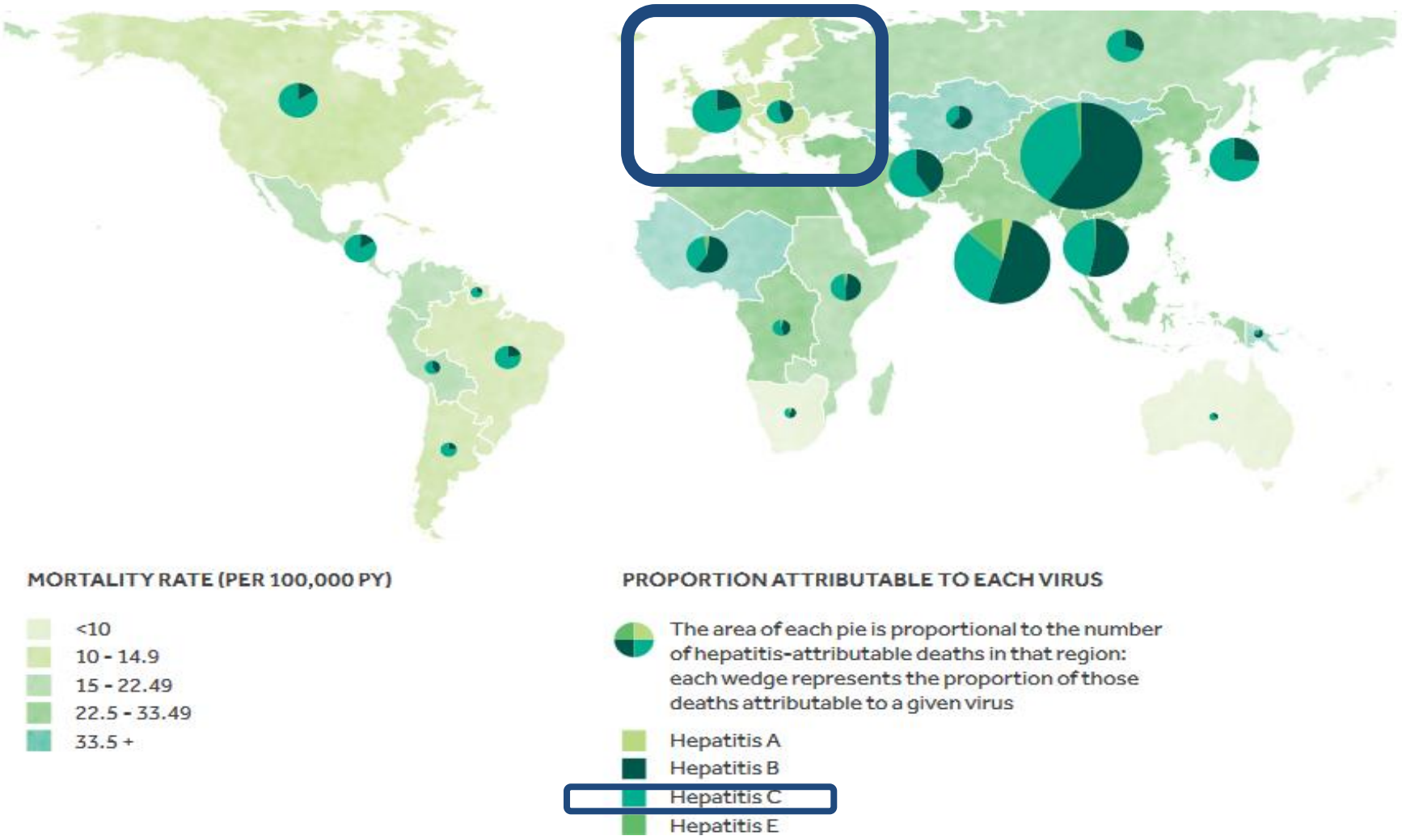
Disclosure

Within the last 36 months:

- Lecturer: Abbvie, Bayer, Gilead, Merck, Sandoz
- Manuscript preparation: Abbvie, Gilead, Merck
- Travel/accommodational meeting expences: Abbvie, Gilead, Merck

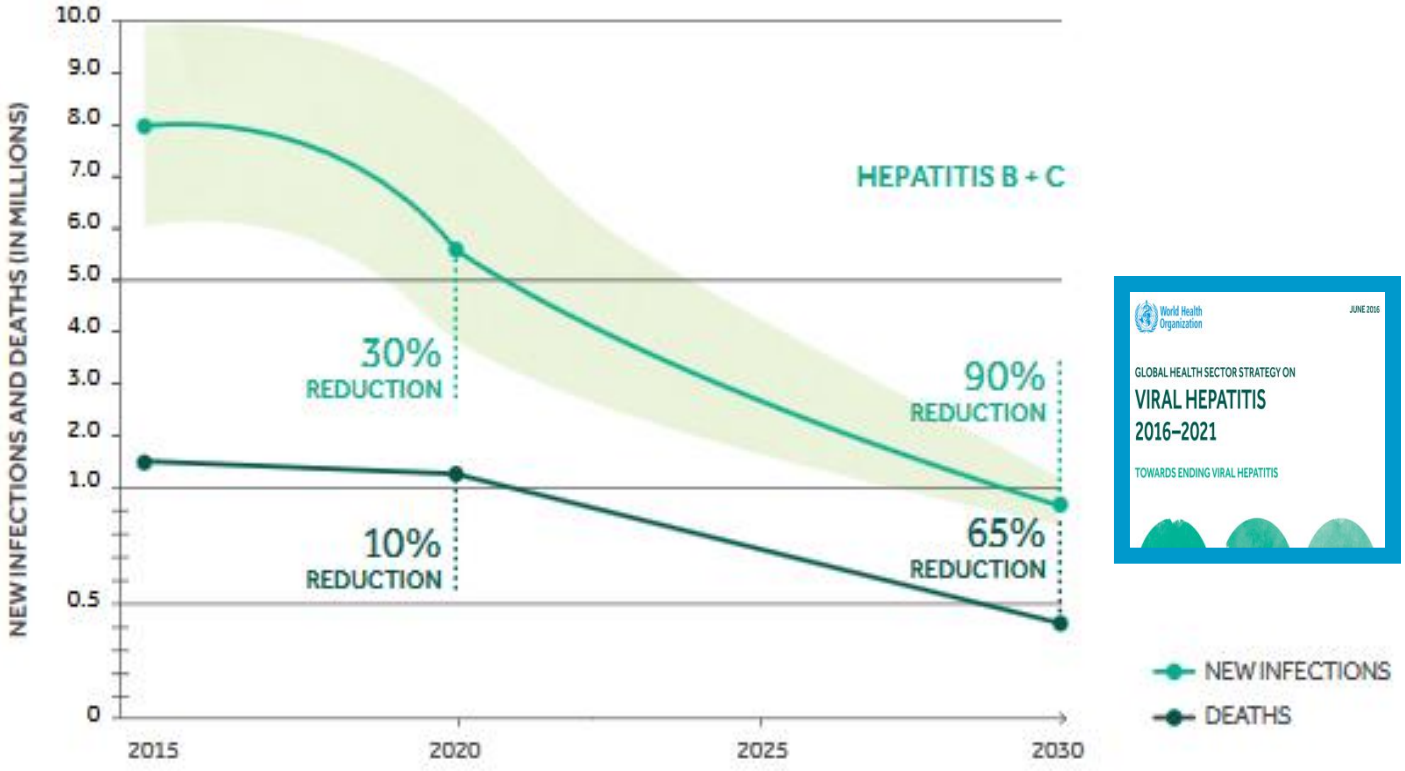
No conflict of interest regarding this presentation

Global number of deaths due to viral hepatitis– hepatitis C is the major problem in Europe



WHO Global hepatitis report, 2017. Available at: http://apps.who.int/iris/bitstream/10665/255017/1/WHO-HIV-2017.06-eng.pdf.

WHO strategy towards elimination of hepatitis C as a public health threat



Goals for reducing new cases of infection and deaths from chronic hepatitis C **by 2030**

WHO. Global Heaplt Sector on Viral Hepatizis. Available at: http//apps.who.int/gb/ebwha/pdf_files/WHA69/A69_32-en.pdf?ua=1

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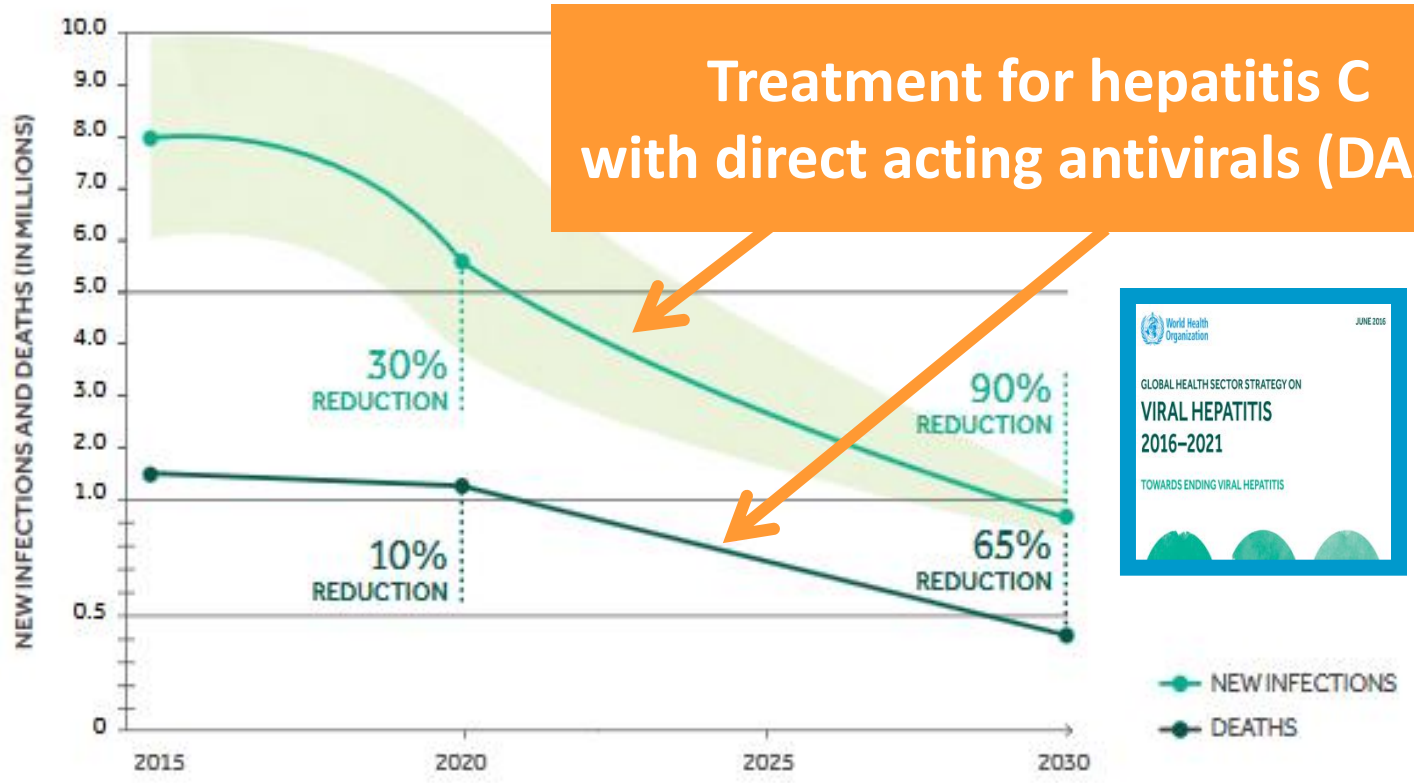

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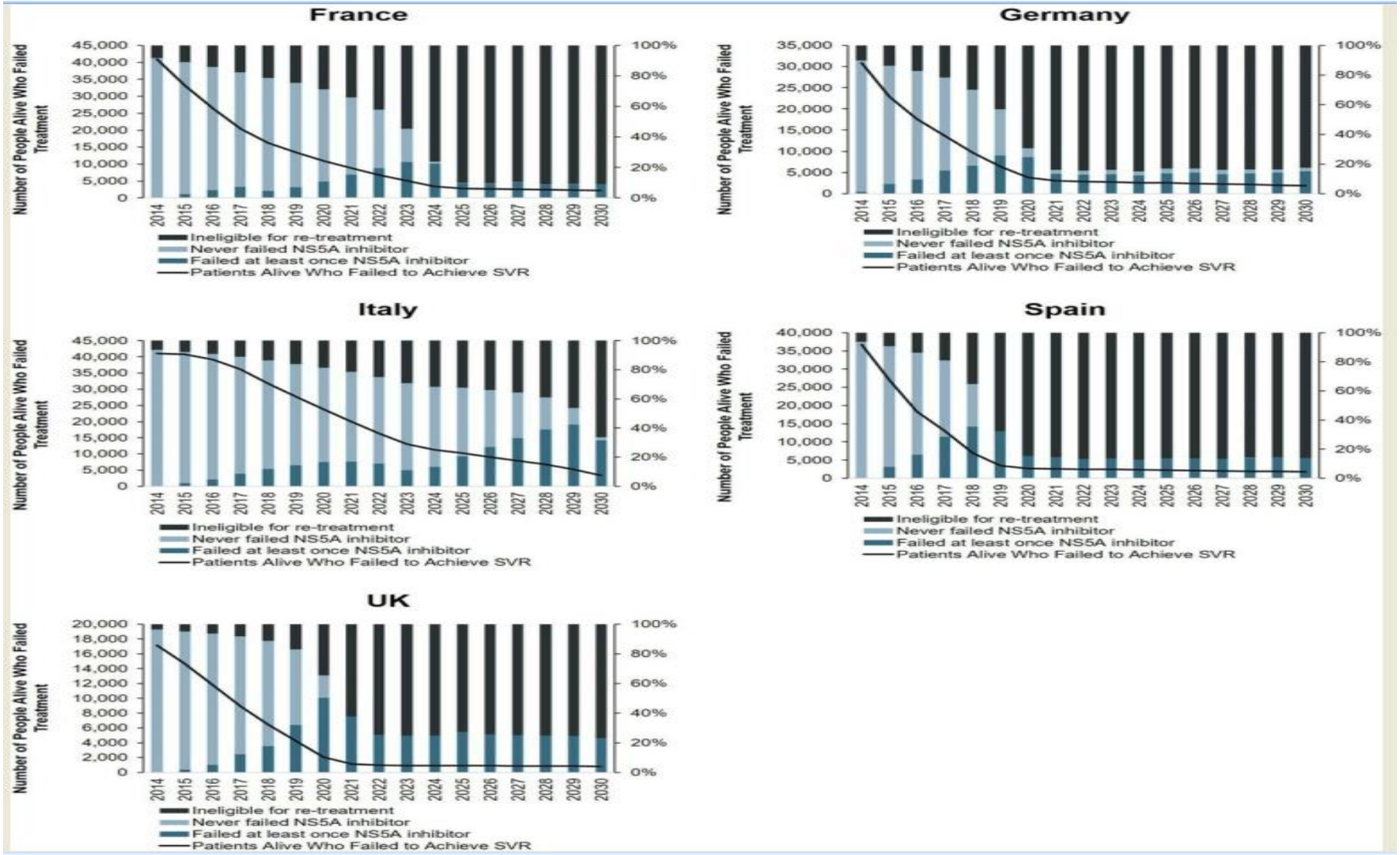
A modeling study

Number of patients alive between 2014 and 2030 who failed to achieve SVR after one or more treatments with DAAs



Chen Q, et al. BMJ Open 2019;9:e026726. doi:10.1136/bmjopen-2018-026726

HCV micro-elimination:
It became feasible in certain populations

Decompensated cirrhotics

Veterans

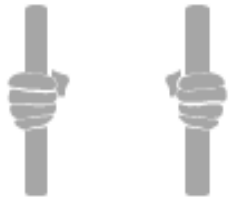
Patients with haemophilia

Patients with chronic kidney disease

Transplant patients

PWID

HIV/HCV co-infected



Incarcerated individuals

Lazarus JV et al. J Hepatol. 2017;67: 665-6.

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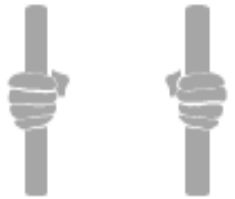


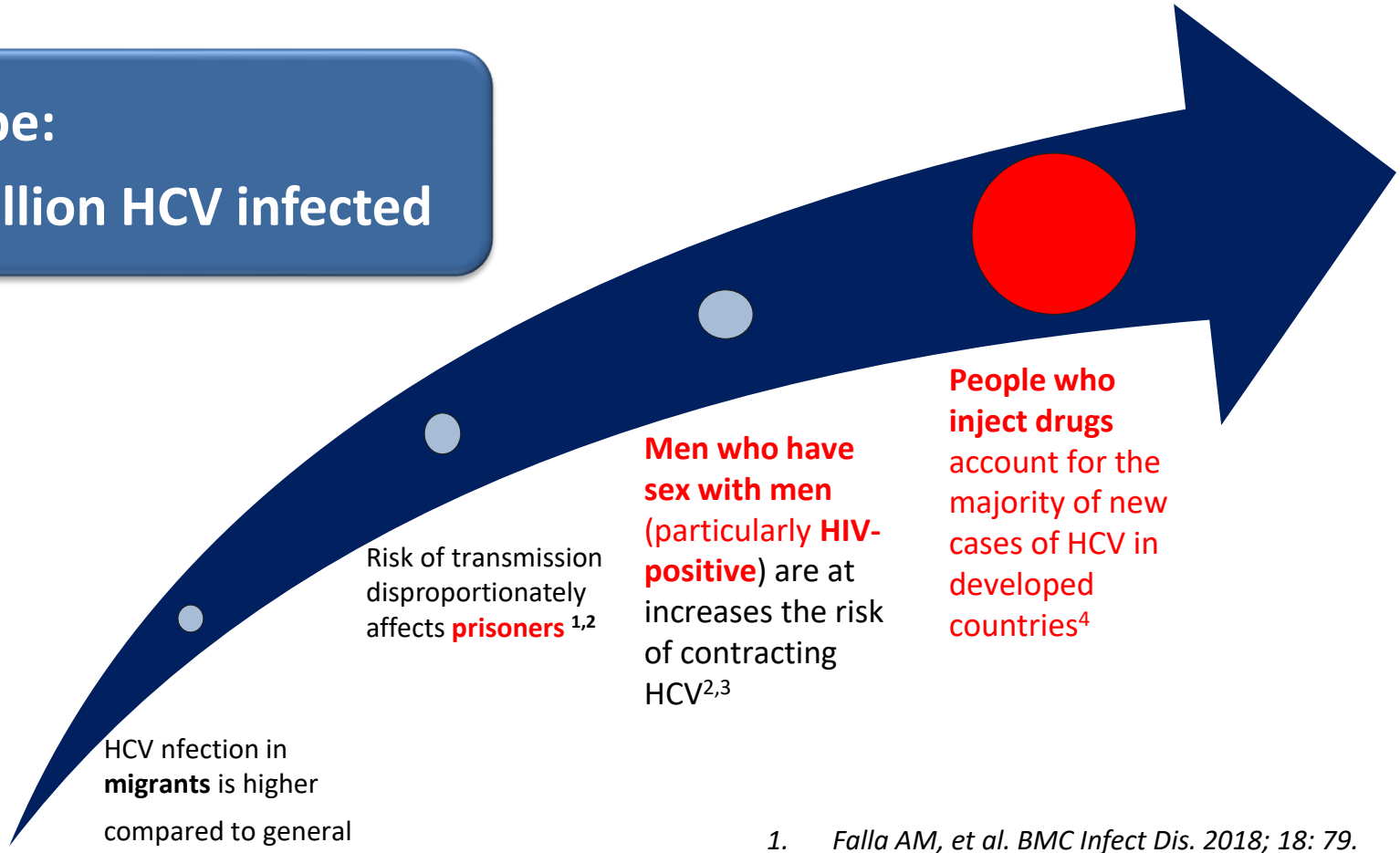
Incarcerated individuals

Lazarus JV et al. J Hepatol. 2017;67: 665-6.

Current RISK GROUPS for HCV infection in EU/EEA

Europe:

14 million HCV infected



HCV nfection in **migrants** is higher compared to general population [1]

Risk of transmission disproportionately affects **prisoners** [1,2]

Men who have sex with men (particularly **HIV-positive**) are at increases the risk of contracting HCV[2,3]

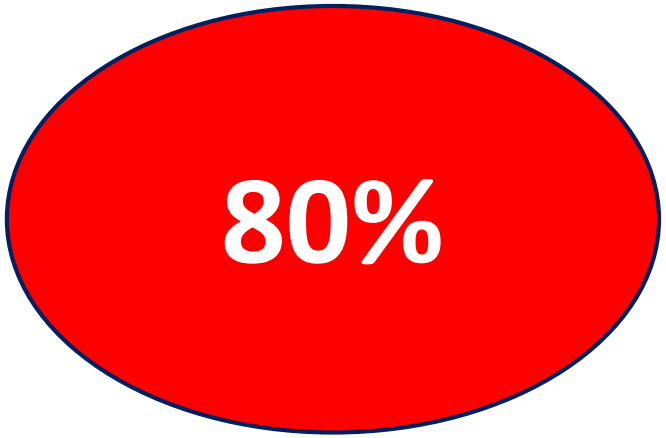
People who inject drugs account for the majority of new cases of HCV in developed countries[4]

1. *Falla AM, et al. BMC Infect Dis. 2018; 18: 79.*
2. *Han R, et al. BMC Infect Dis 2019; 19: 655.*
3. *Larsen C, et al. PLoS One. 2011;**6:**1-9.*
4. *Shepard CW, et al. Lancet Infect Dis. 2005;**5:**558-567.*

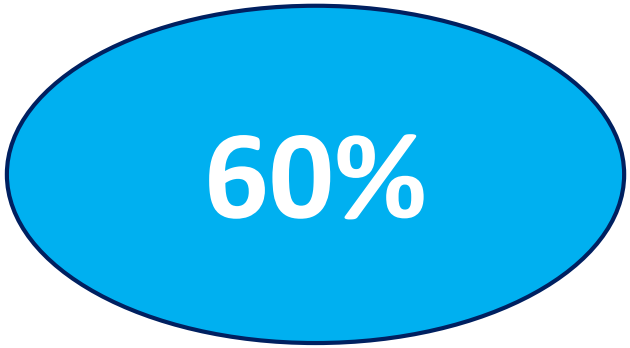
WHO Global hepatitis report, 2017. Available at: http://apps.who.int/iris/bitstream/10665/255017/1/WHO-HIV-2017.06-eng.pdf.

PWID are the driving force of HCV epidemic in EUROPE

Europe	Anti-HCV+ prevalence (%)	Anti-HCV+ (N)
Western	53 %	0.5 million
Eastern	65 %	1.9 million



of new HCV infections



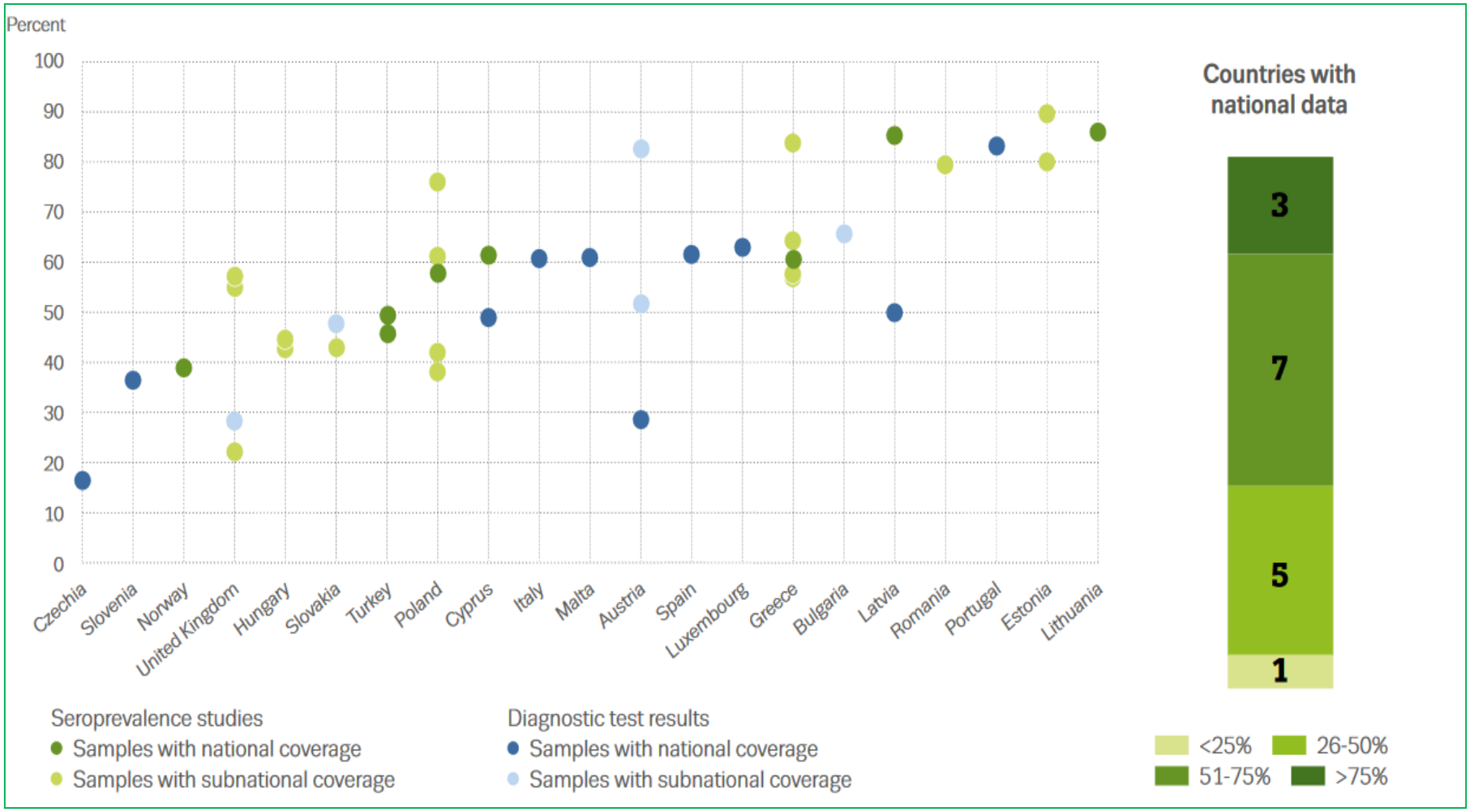
of existing HCV infections

EMCDDA 2017. European Drug Report : Trends and Developments. http://www.emcdda.europa.eu/system/files/publications/4541/TDAT17001ENN.pdf

The Boston Consulting Group. Road to Elimination: Barriers and Best Practices in Hepatitis C Management. July 2017. Accessed 5 July 2018

World Hepatitis Alliance. http://www.worldhepatitisalliance.org/sites/default/files/resources/documents/holding_governments_accountable_-_civil_society_survey_report.pdf.

HCV-seroprevalence and diagnostic test results among PWID in Europe

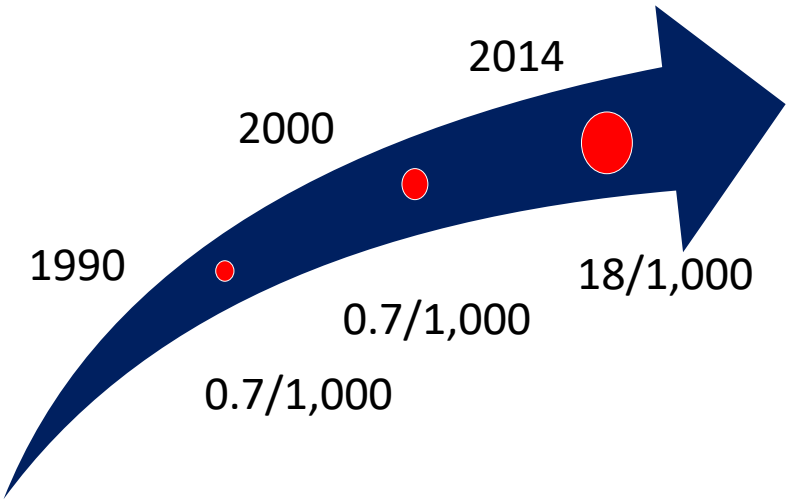


EMCDDA (2020), European Drug Report 2020: Trends and Developments, Publications Office of the European Union, Luxembourg

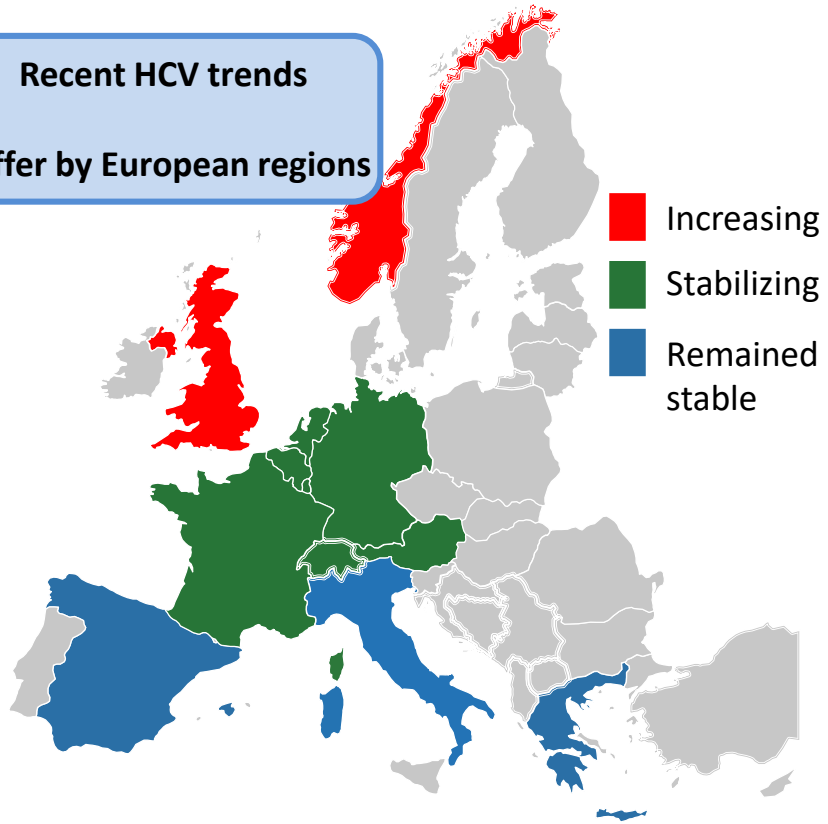
Increased incidence of HCV infection in **HIV-positive MSM** in Europe

HCV incidence was measured among 5,941 HIV-positive MSM from the CASCADE Collaboration (Period: 1990–2014)

HCV incidence per 1,000 person-years increased over the last 25 years

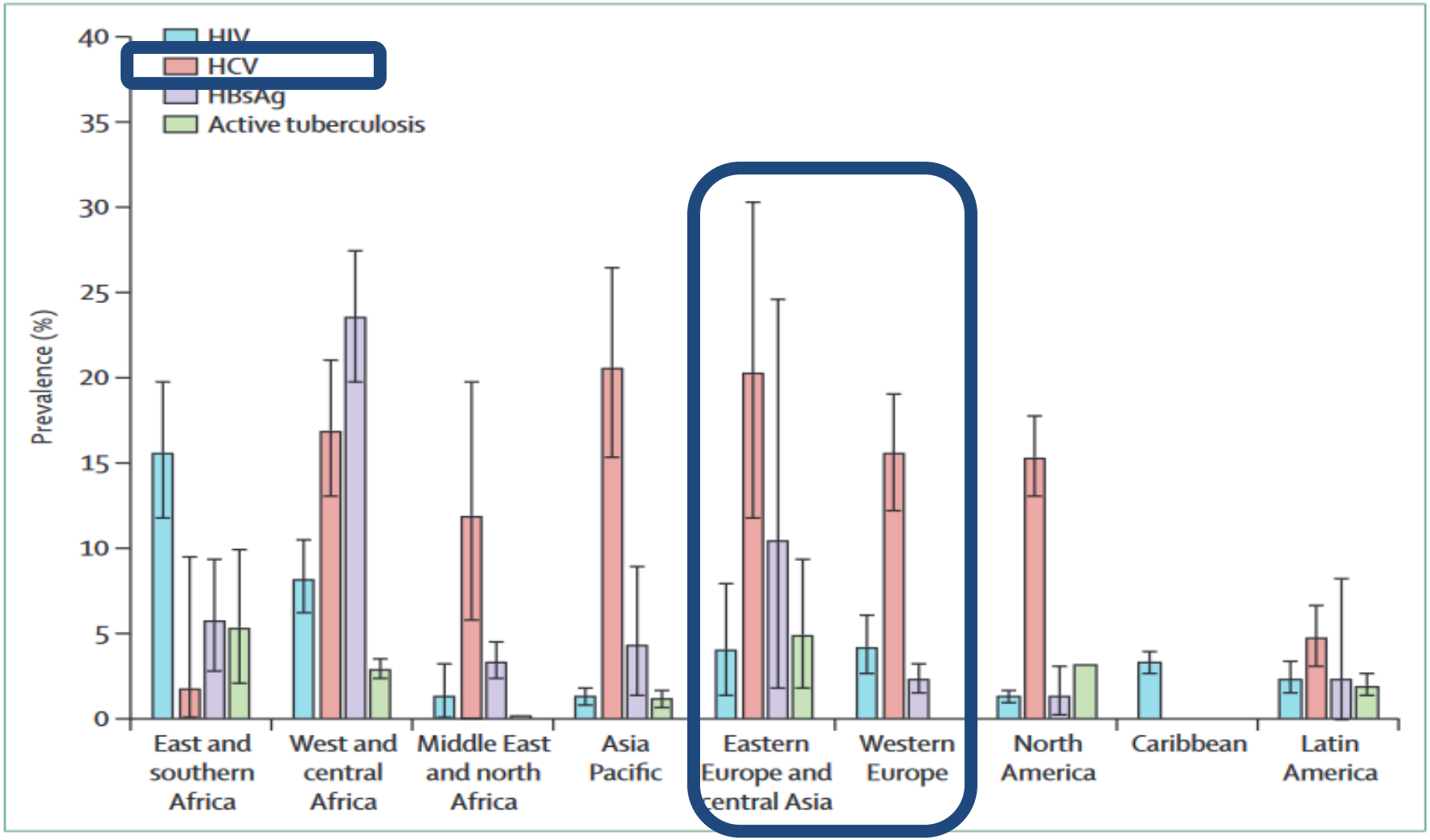


Recent HCV trends differ by European regions



Katinka van Santan D, et al. J Hepatol. 2017;67:255-62.

Reported prevalences of four infectious diseases among prisoners worldwide



Dolan K, et al. Lancet 2016; 388: 1089-109.

HIV – HCV

Globally,
among **37.9 million PLHIV**
and
71 million with chronic HCV

There are approximately
2.3 million HIV/HCV
co-infected individuals world-wide

Of these, **1.36 million** are **persons who currently inject drugs**

The est. global **prevalence** of **HCV** in PLHIV is **6.2%**

The prevalence of HCV co-**infection varies greatly across different groups** of PLHIV:

- **in persons who inject drugs** (**82.4%**),
- men who have sex with men (**6.4%**),
- without higher risk behaviours (2.4%)

Eastern Europe and central Asia account for the largest proportion of PLWH who have serological **evidence of past or present HCV** infection (**27%**), because of **injection drug use**

WHO Global hepatitis report, 2017. Available at: http://apps.who.int/iris/bitstream/10665/255017/1/WHO-HIV-2017.06-eng.pdf.
UNAIDS/WHO estimates, 2018.
Platt L, et al. Lancet Inf Dis 2016; 16:797–808.
Basnayake SK, Easterbrook PJ. J Viral Hep 2016; 23:545–59.

DAA Therapy of HCV in PWID

A Systematic Review and Meta-analysis

38 studies, 3634 pts with DU in the past 6 months, initiation/during DAA

	Studies	Participants	Tx Completion	SVR
Recent DU	21	1408	97·5%	**87·7%**
OST	36	2987	97·4%	**90·7%**
Recent injecting DU	8	670	96·9%	**87·4%**

Meta-regression analysis: clinical trials (*vs* observational studies) and higher age were associated with higher SVR and lower % lost to follow-up.

Hajarizadeh B, et al. Lancet Gastro Hepatol 2018; 3: P731-2.

High cure rates of hepatitis C with G/P among HIV/HCV co-infected MSM in Swiss HIV cohort study

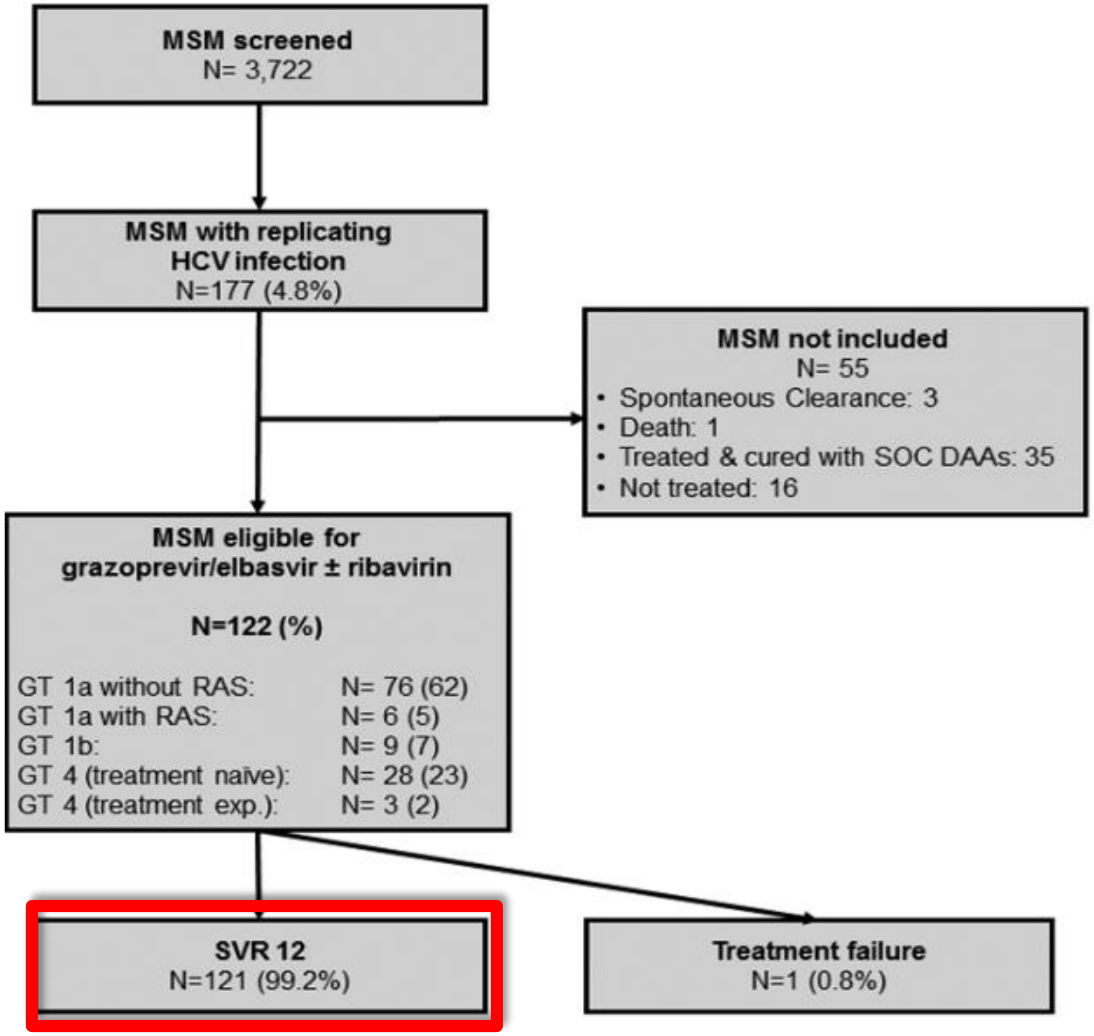

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America hivma hiv medicine association

High Cure Rates With Grazoprevir-Elbasvir With or Without Ribavirin Guided by Genotypic Resistance Testing Among Human Immunodeficiency Virus/Hepatitis C Virus–coinfected Men Who Have Sex With Men

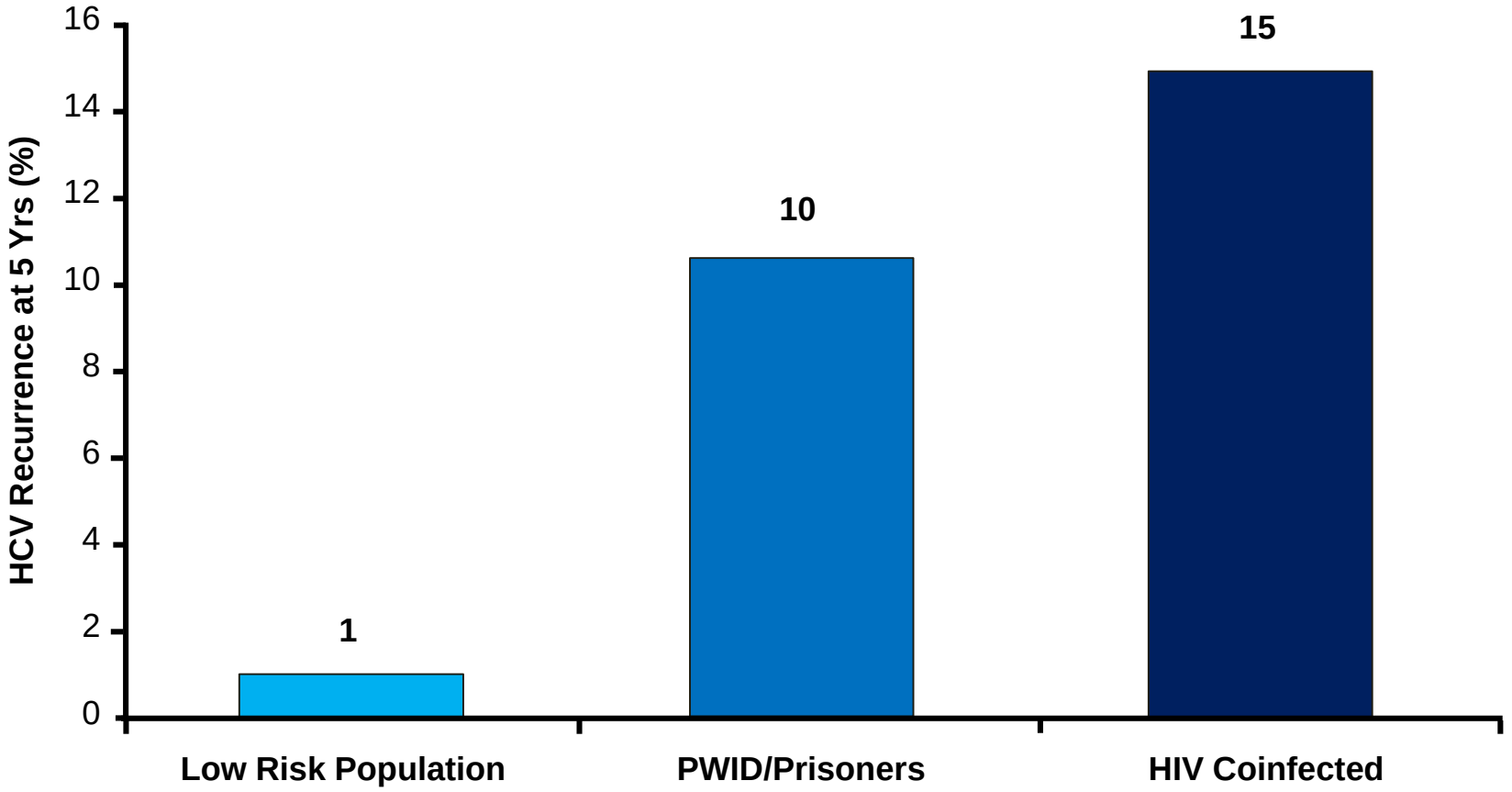
Dominique L. Braun, Benjamin Hampel, Roger Kouyos, Huyen Nguyen, Cyril Shah, Markus Flepp, Marcel Stöckle, Anna Conen, Charles Béguelin, Patrizia Künzler-Heule, Dunja Nicca, Patrick Schmid, Julie Delaloye, Mathieu Rougemont, Enos Bernasconi, Andri Rauch, Huldrych F. Günthard, Jürg Böni, Jan S. Fehr, and the Swiss HIV Cohort Study



Braun D, et al. CID 2018; 68: 569-76.

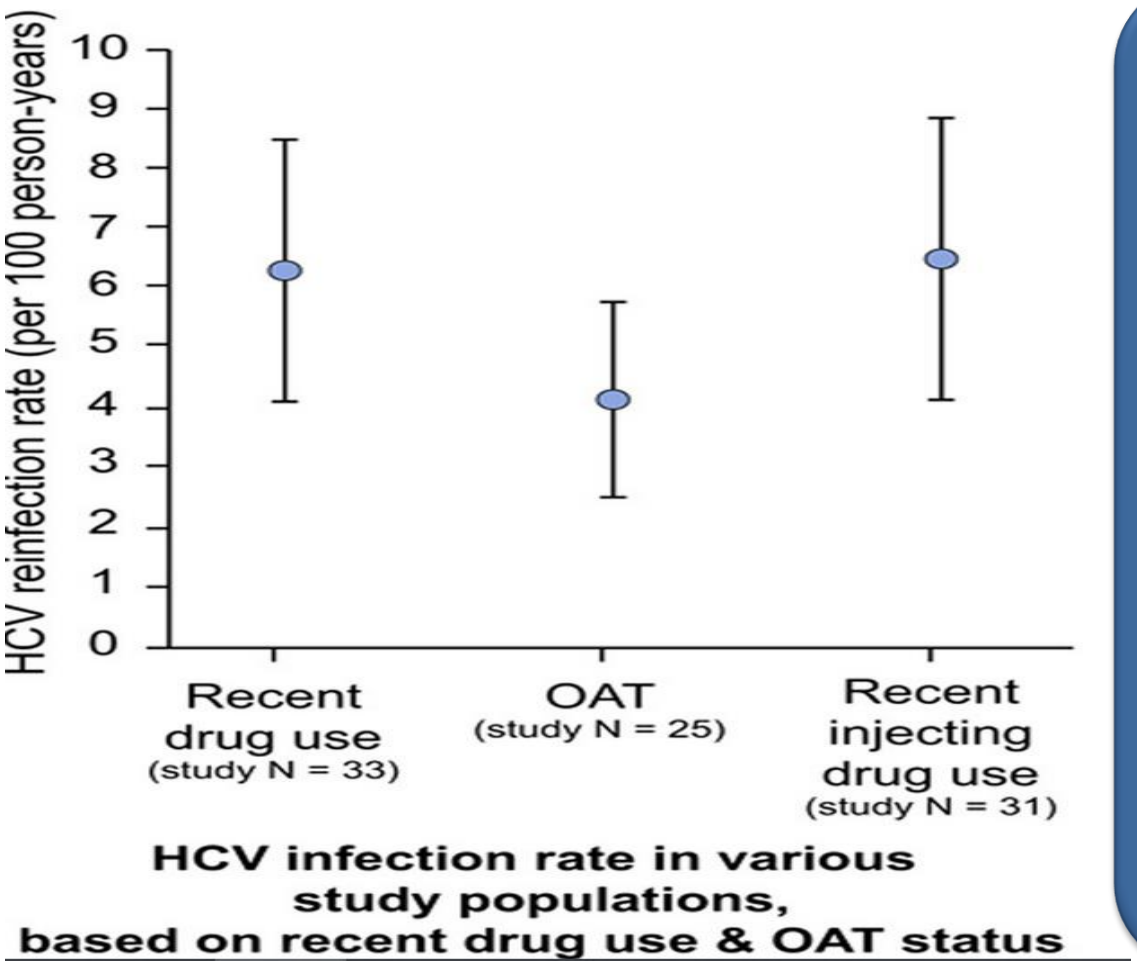
HCV Re-infection over 5 yrs by study population

a systematic review and meta-analysis



*Simmons B, et al. Clin Infect Dis **2016**: 62: 683-94.*

Hepatitis C reinfection after successful antiviral treatment among PWID: A meta-analysis of 36 studies



HCV infection rate in various study populations, based on recent drug use & OAT status

- Follow-up of 6.311 person-years (p-y)

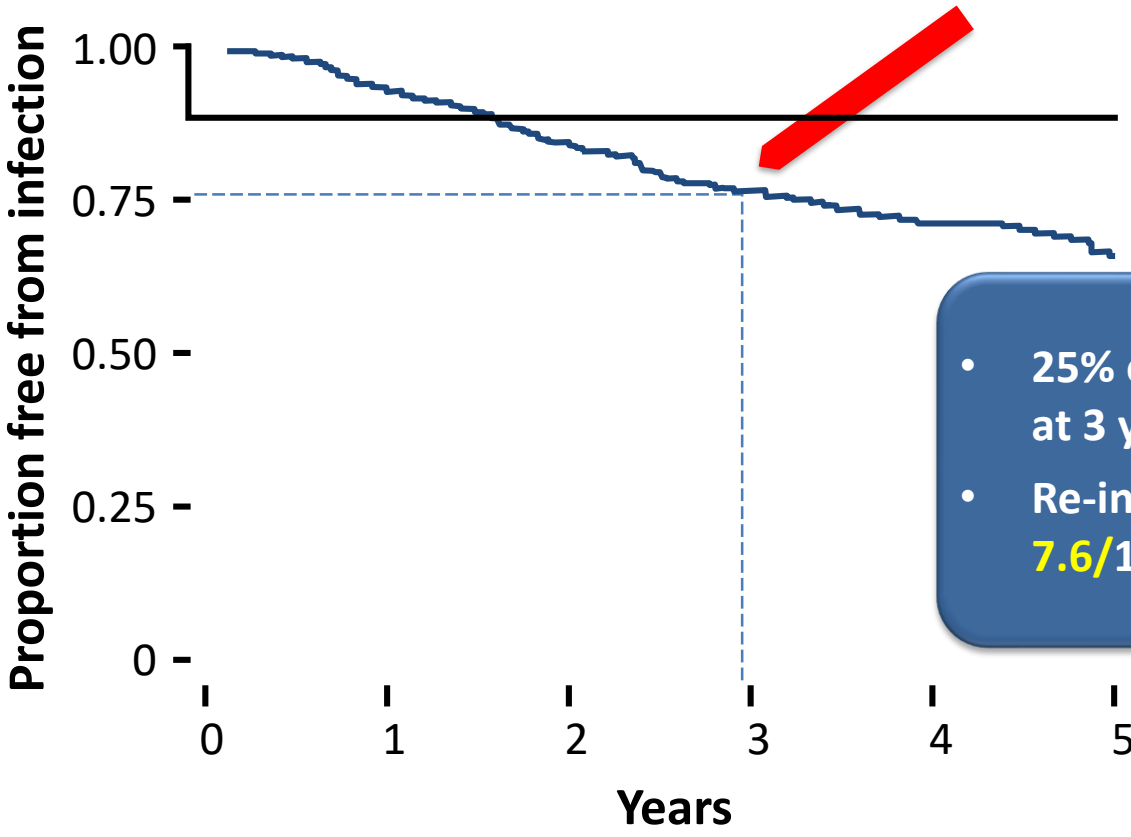
Overall rate of re-infection:

- recent drug use: **5.9/100 p-y**
- recent injecting: **6.2/100 p-y**
- on OST: **3.8/100 p-y**

Hajarizaadeh B, et al. J Hepatol 2020; 72: 643-57.

High risk of HCV re-Infection in HIV-positive MSM in Western Europe

Data from the European AIDS Treatment Network (NEAT) consortium centres in Western Europe (UK, Germany, Austria and France)



- 25% of MSM re-infected at 3 years
- Re-infection incidence of 7.6/100 person-years

*Martin TC, et al. J Hepatology **2016**; 64:S138–139..*

Prevention of HCV transmission in risk groups

- Several **effective strategies exist for reducing transmission of HCV in risk groups:**
  - needle /syringe exchange programs (N/S)
  - safe injection facilities
  - opioid substitution treatment (OST)
  - safe sex practices

- HCV incidence **remains fairly high** even in areas with such programs

- Experiences from **HIV infection**:
  - early initiation of ART benefits in preventing HIV transmission

- <u>The proposed new strategies for prevention of HCV transmision :</u>
  - **Treatment as prevention (TAP)**

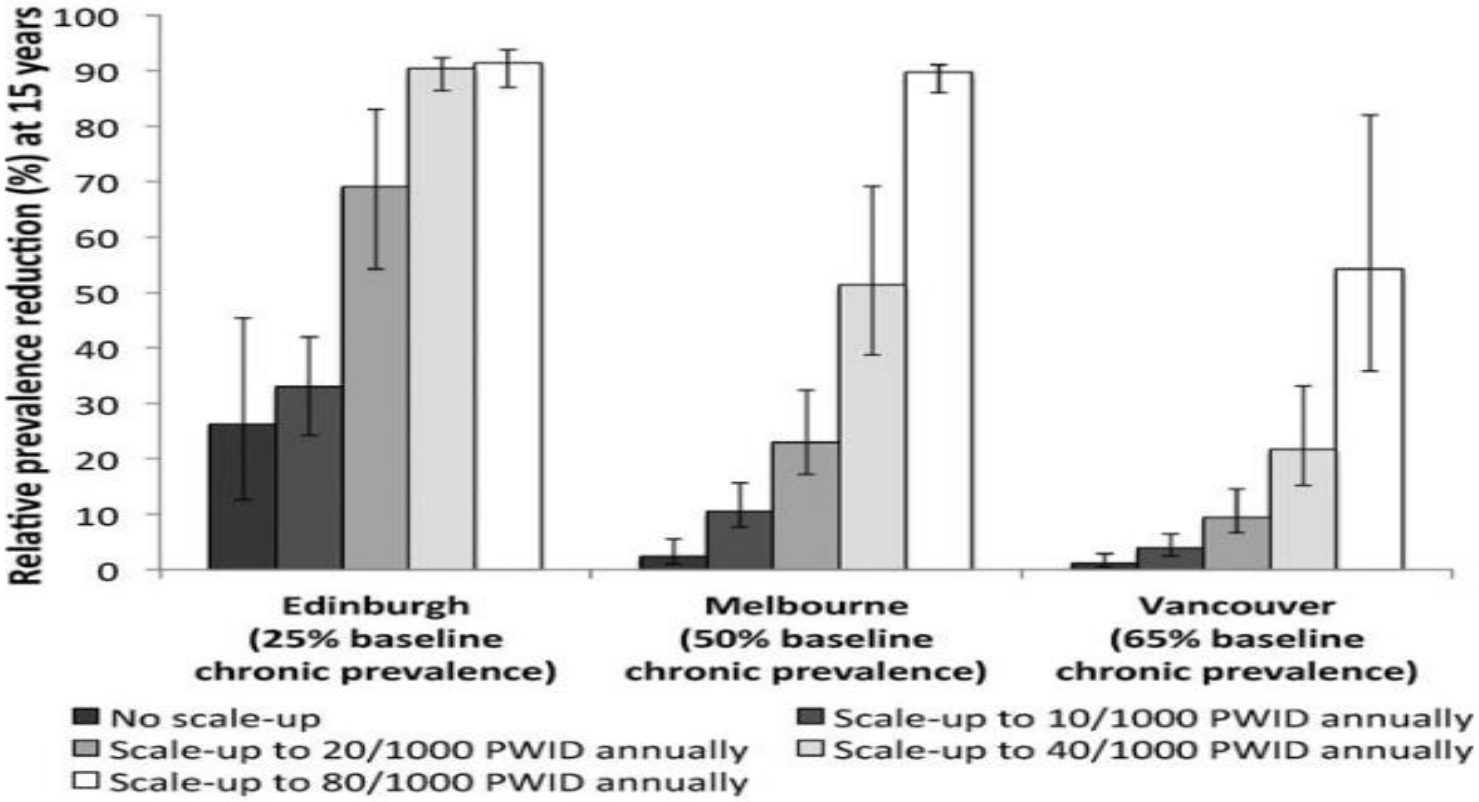
http://whqlibdoc.who.int/publications/2009/9789241597760_eng.pdf
Brauneau et al. Clin Infect Dis 2014; 58(6):755-61.

http://www.who.int/hiv/pub/guidelines/hepatitis/en/index.html
Martin JK et al. J Hepatol, 2011;54: 1137-44.

HCV Treatment as Preventon (TAP)

- Are DAAs effective on the **public-health level?**
  - modeling studies
  - real-life data

Hepatitis C Virus TAP Among PWID: Modeling Treatment Scale-Up in the Age of DAAs

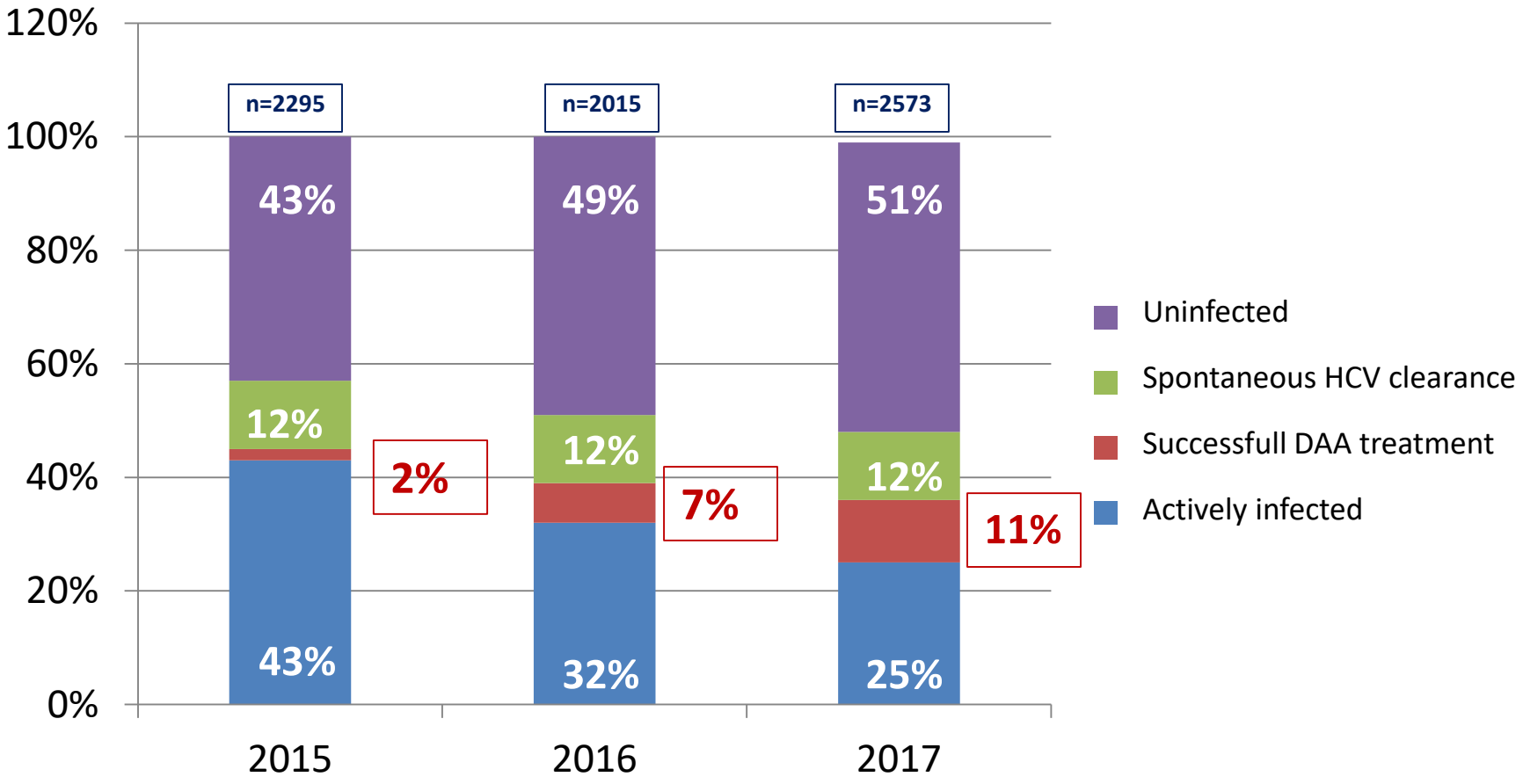


Relative prevalence reductions at 15 years by scaling-up DAA treatment

*Martin NK, et al. Hepatology **2013**; 58: 1598-1609.*

Association between rapid utilisation of DAAs and decline in the prevalence of viremia among PWID in N/S programmes

A national study from Australia



Number of PWID in N/S programmes with regards to HCV infection

*Iversen J et al. J Hepatol **2019**; 70: 33-9.*

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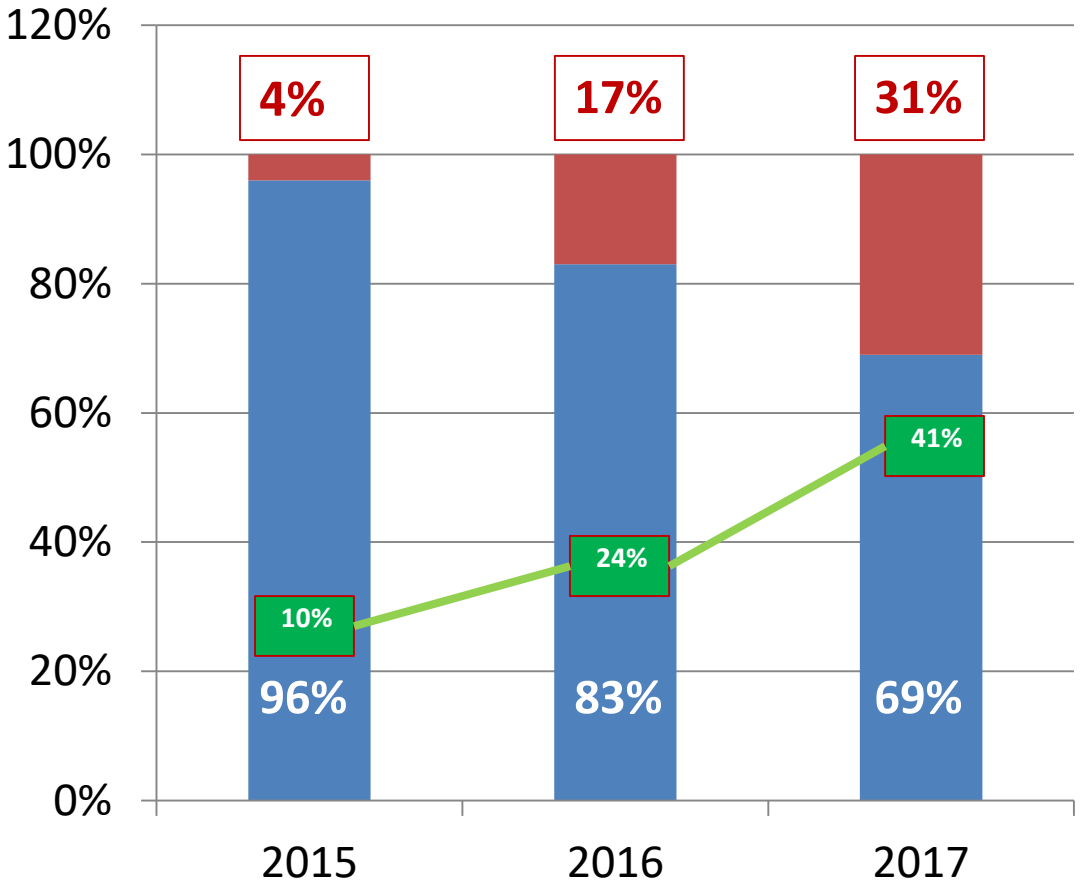

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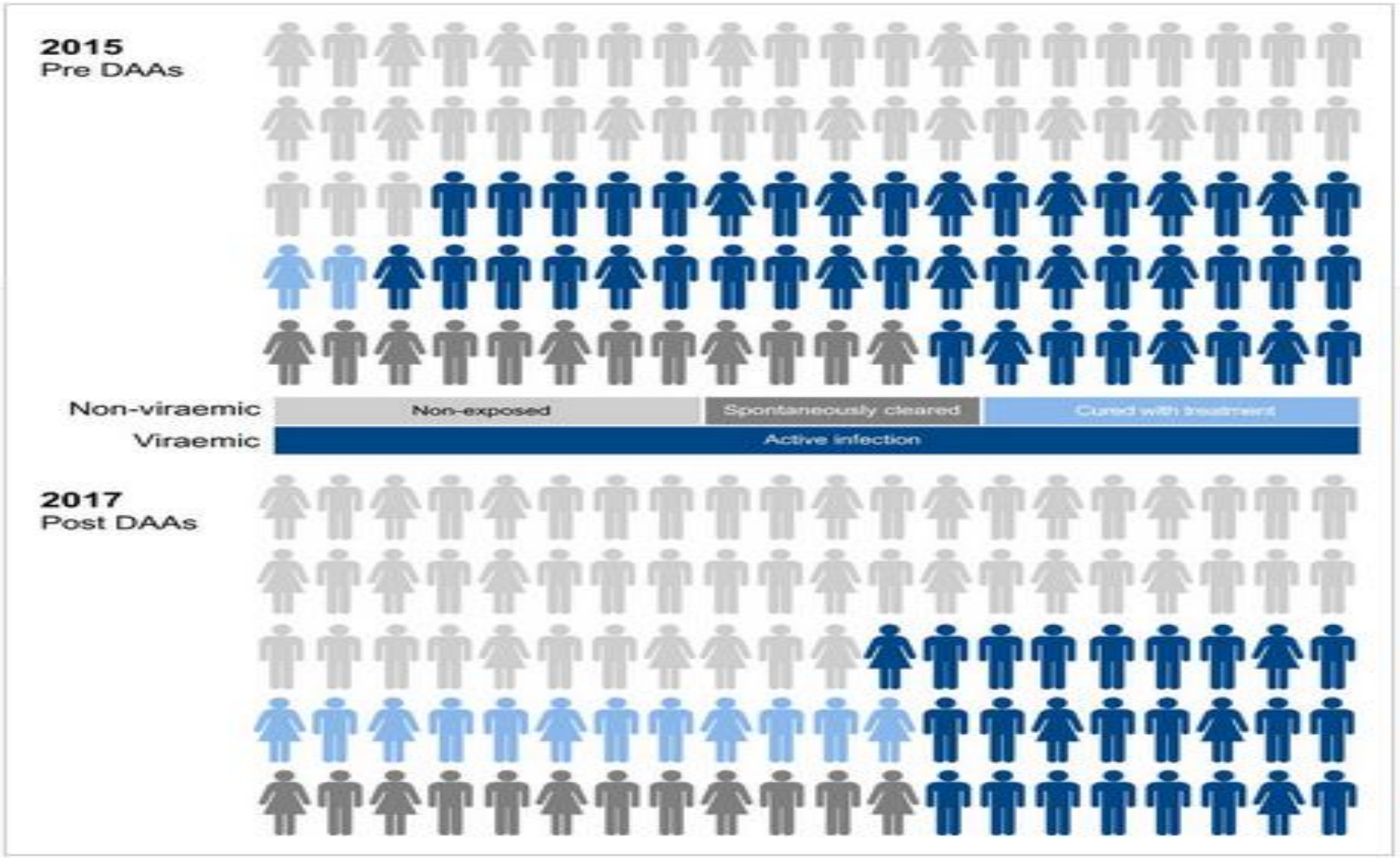

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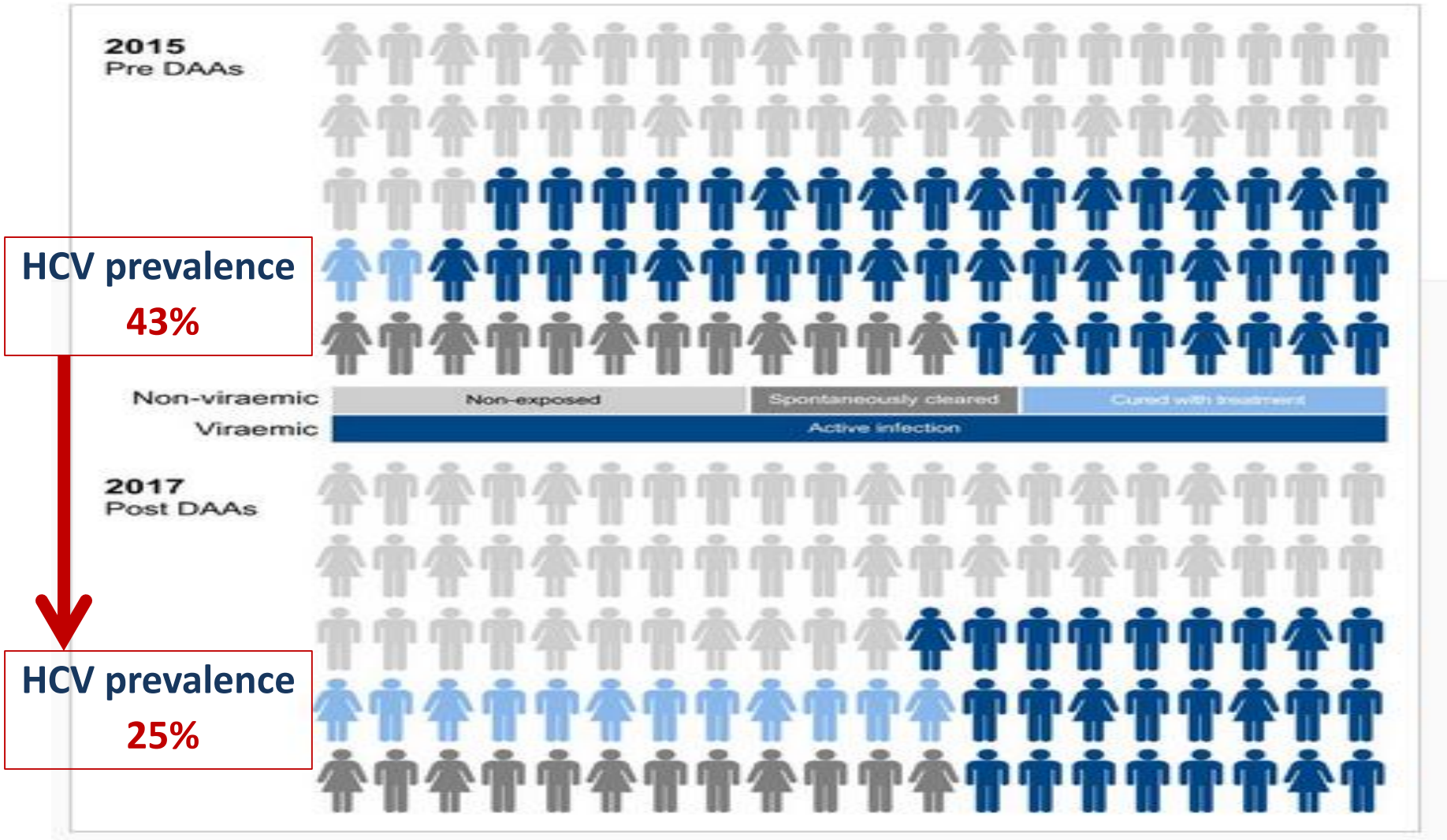
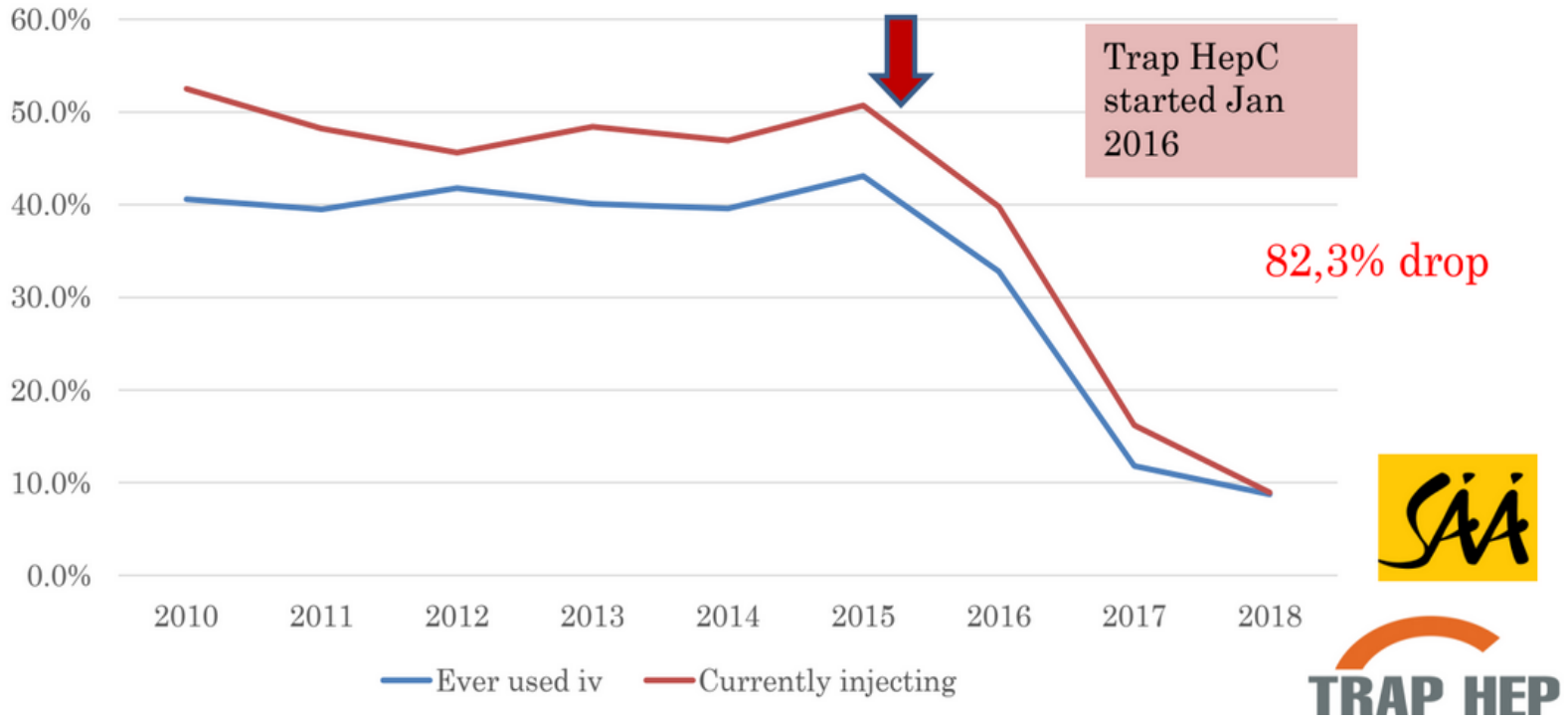


*Iversen J et al. J Hepatol **2019**; 70: 33-9.*

HCV RNA prevalence decline in PWID at Addiction Hospital in Iceland

When TraPHepC was initiated in 2016:

- All PWID were screened, diagnosed and subsequently treated with DAAs



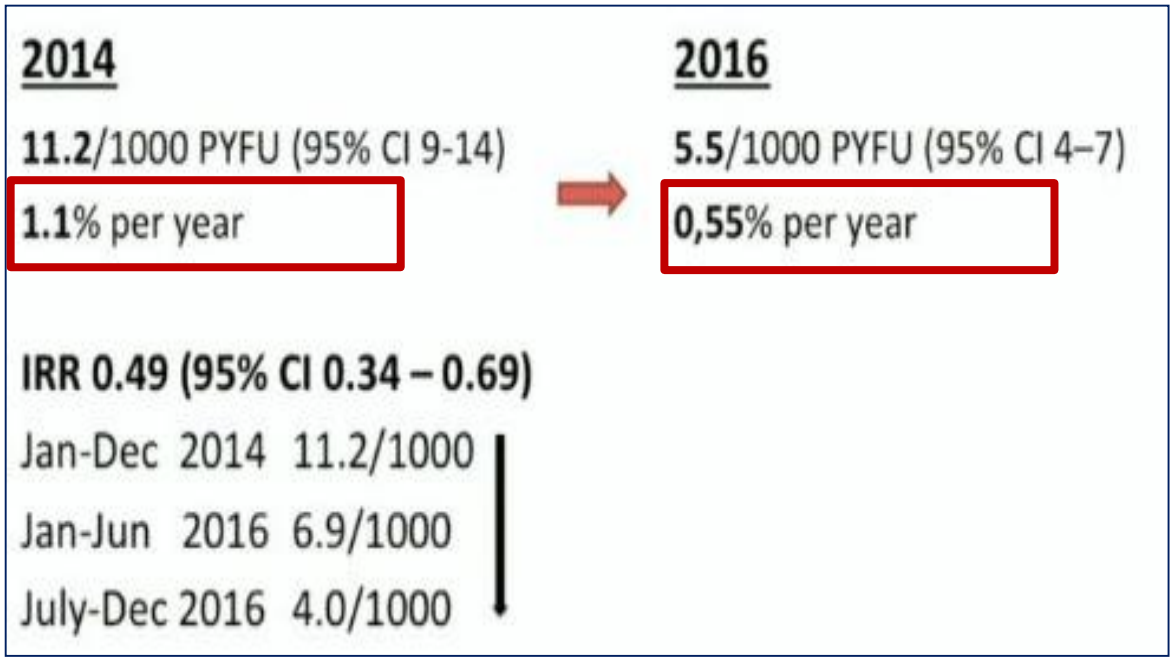
Tyrfigsson, et al. INHSU 2018.

*Olafsson S. First Regional Consultation on Viral Hepatitis in the WHO EuropeanRegion: Progress on the Way to Elimination. Tbilisi, Georgia 11–13 February **2019**.*

Real-life data from the Netherlands

A substantial decline in acute HCV infections among HIV-positive MSM after DAA roll out

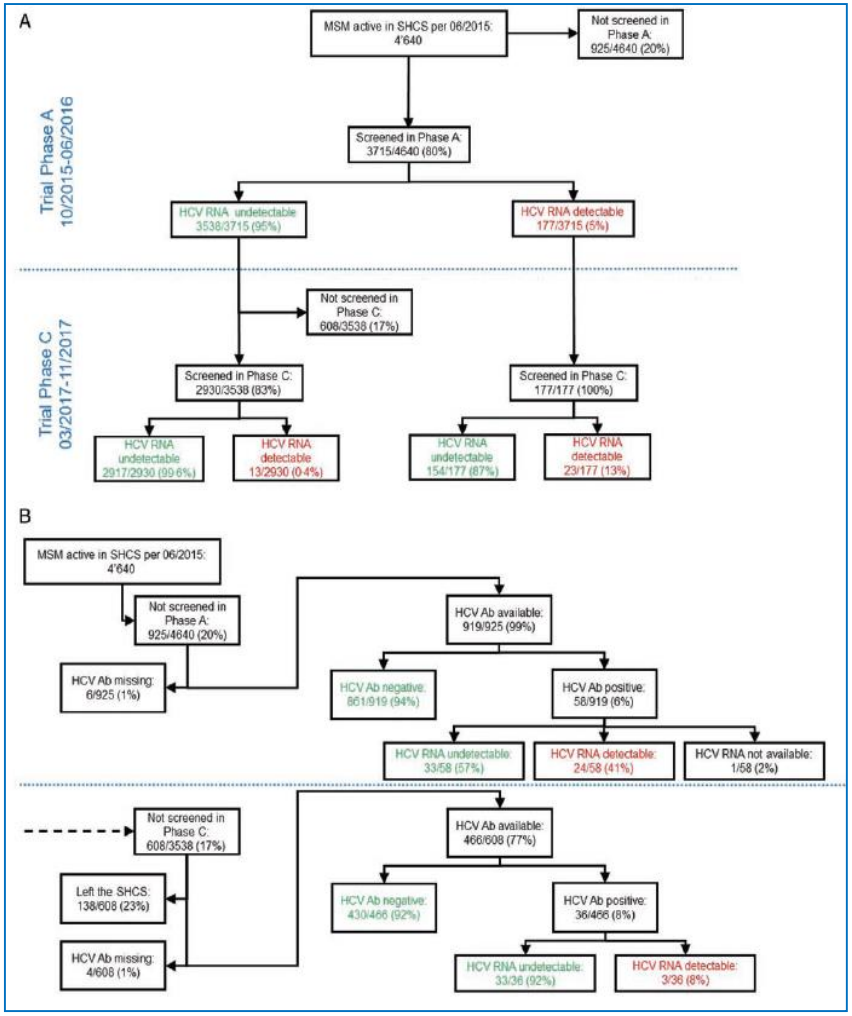
One year after unrestricted DAA availability in the Netherlands, the incidence of acute HCV in HIV+ MSM decreased by 52%



For the first time, real-life data show that "HCV treatment as prevention'" averts new HCV infections in HIV+MSM

Boerekamps A, et al. Abstract 137LB. CROI 2017.

TAP trial to eliminate hepatitis C among HIV-positive MSM in the Swiss HIV Cohort Study



A systematic, population-based HCV micro-elimination program among MSM living with HIV

Phase A (**10/2015**–06/2016):
a population-based and systematic screening for HCV-RNA among MSM from the SHCS.

Phase B (06/2016–02/2017):
treatment with DAAs offered to MSM identified with a replicating HCV infection.

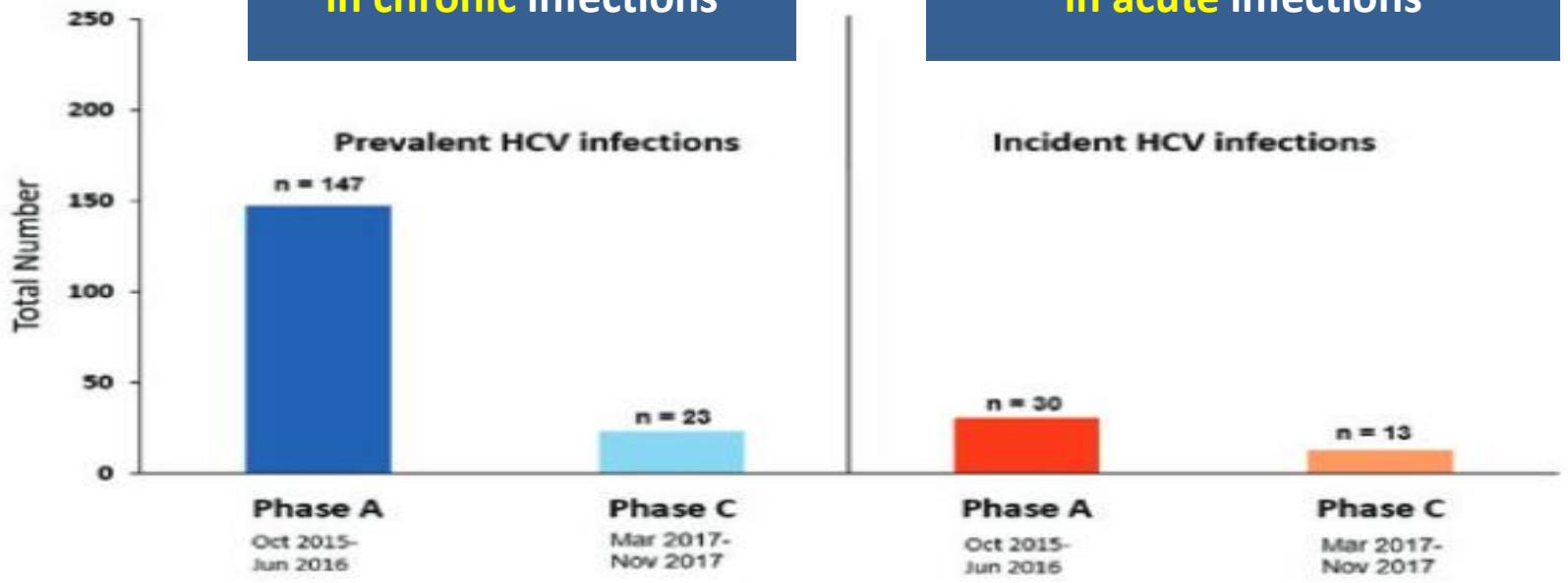
Phase C (03/2017–**11/2017**):
re-screening offered to all MSM for HCV-RNA and initiated DAA treatment in MSM with replicating infections

Braun DL, et al. Clin Infect Dis. ***2020*** *Aug 6:ciaa1124. doi: 10.1093/cid/ciaa1124.*

TAP trial to eliminate hepatitis C among HIV-positive MSM in the Swiss HIV Cohort Study

84% decrease in chronic infections

57% decrease in acute infections



A/ Primary screened: 3715/4640 (80%); 177 HCV RNA-positive (4.8%);

B/ Treatment: 150 started DAA (85%), 149 cured (99.3%)

C/ Re-screened: 2930/3538 (83%); **13 new infections (0.4%)**

- Cured: 176/190 (93%)

Braun DL, et al. Clin Infect Dis. ***2020*** *Aug 6:ciaa1124. doi: 10.1093/cid/ciaa1124.*

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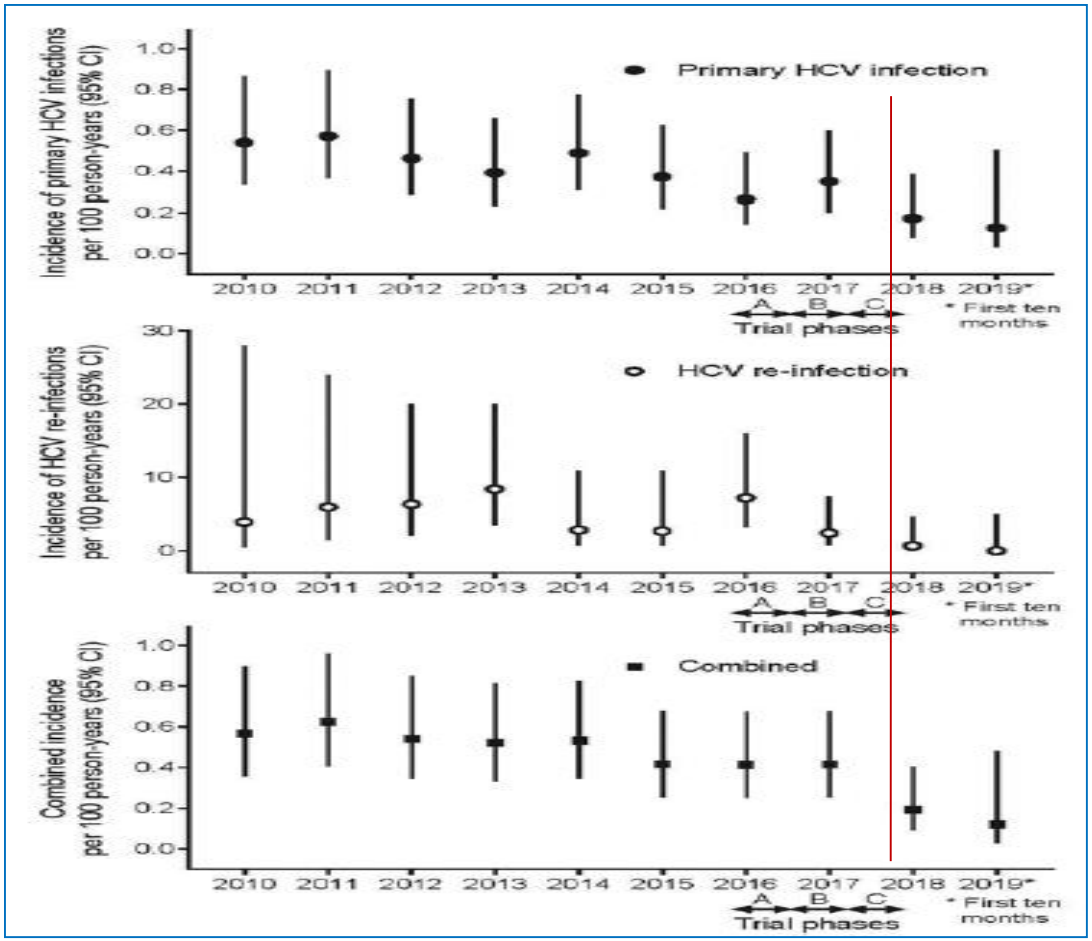

Combined incidence of HCV infection per 100 py (95% CI)

DECLINE, 2015-2017:

0.53/100 p-y

↓

0.12/100p-y

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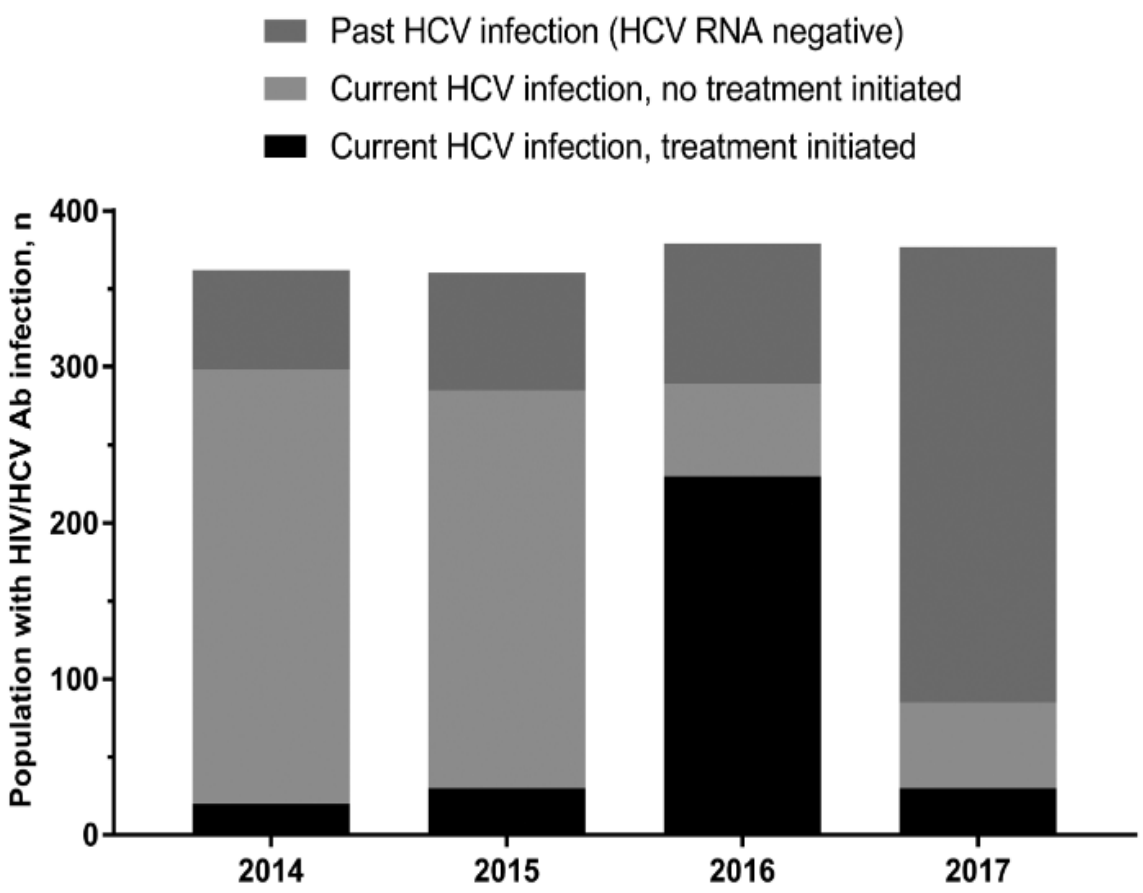
Universal access to DAAs was available in Switzerland from **October 2017.**

Braun DL, et al. Clin Infect Dis. ***2020*** *Aug 6:ciaa1124. doi: 10.1093/cid/ciaa1124.*

Hepatitis C Microelimination Among HIV/HCV coinfected in Australia: The CEASE Study



Annual HCV treatment uptake, 2014–2017

- **Period:** 2014-2017
- **N**=402
- 95% male
  (80% gay, bisexual)
- 80% IDU
  (39% currently injecting)

Treatment uptake:
2014: 7%
2015:11%
2016: 80%
Cumulative: **91%**

*Martinello M, et al. Clin Infect Dis **2020** Sep 12;71(6):1502-10.*

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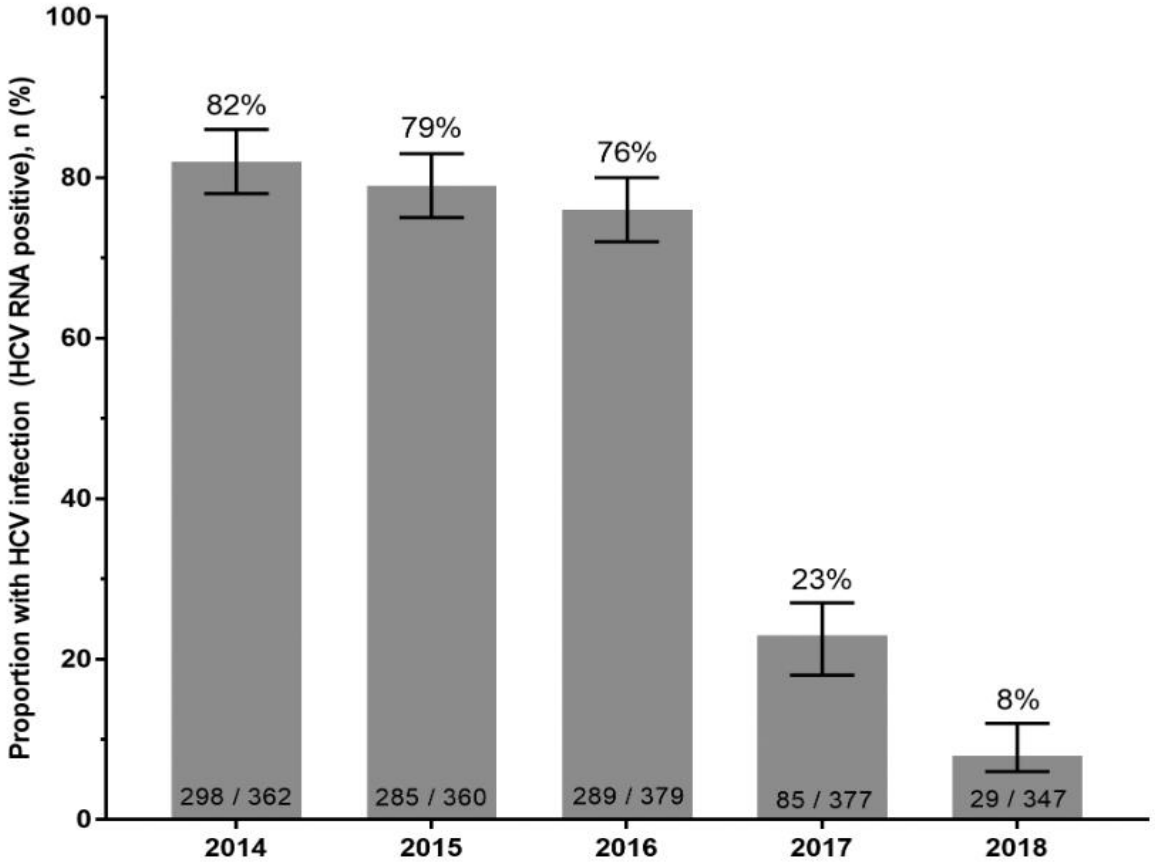


Proportion of the CEASE cohort with HCV infection (HCV RNA positive), 2014–2018.

Decline in HCV prevalence from 2014 to 2018:

82% ↓ **8%**

Reinfection:

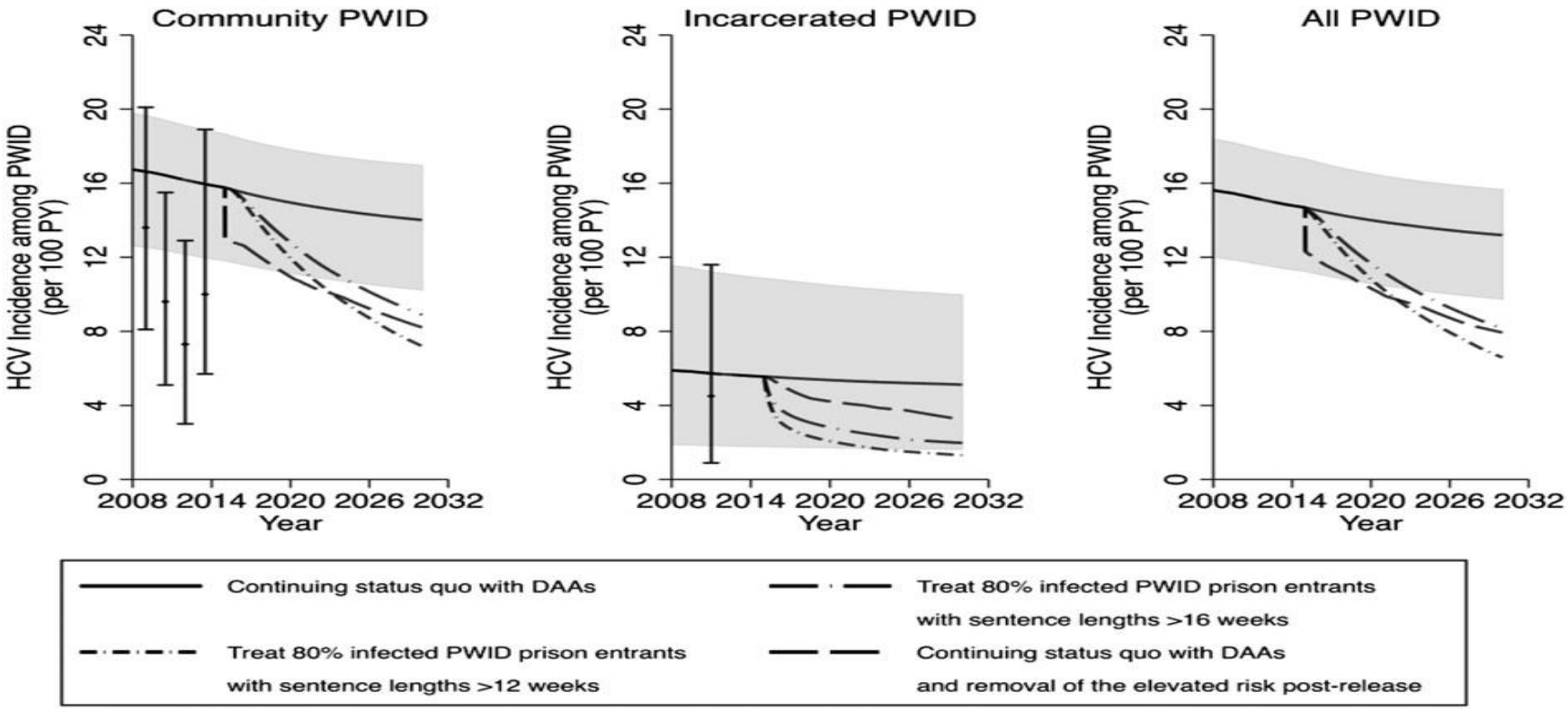
n=5

0.81/100 py

*Martinello M, et al. Clin Infect Dis **2020** Sep 12;71(6):1502-10.*

Modeling
the impact of incarceration and prison-based HCV treatment on HCV transmission among PWID in Scotland

National survey of HCV incidence in PWID: in community 7.3%, in prisons 4.3% -
but 2.3-fold elevated transmission risk among recently released PWID (<6mths)
Incarceration contributes 28% of HCV transmission among PWID in Scotland.



Stone J, et al. Addiction 2017; 112: 1302–14.

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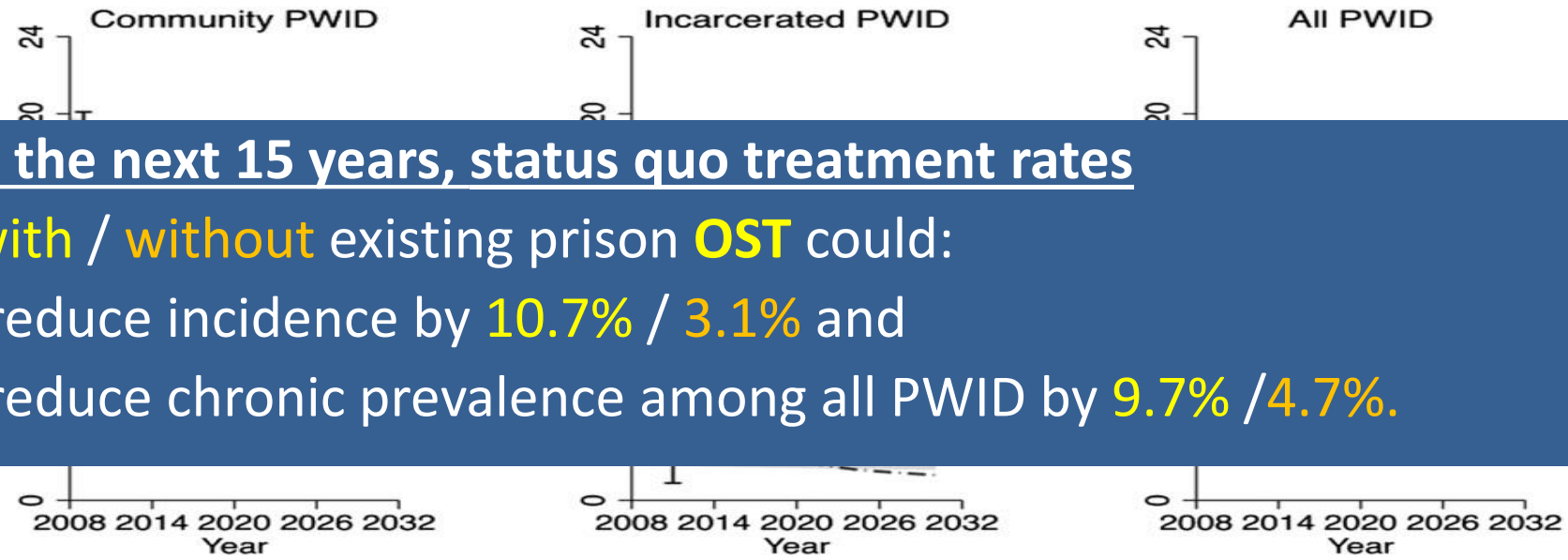


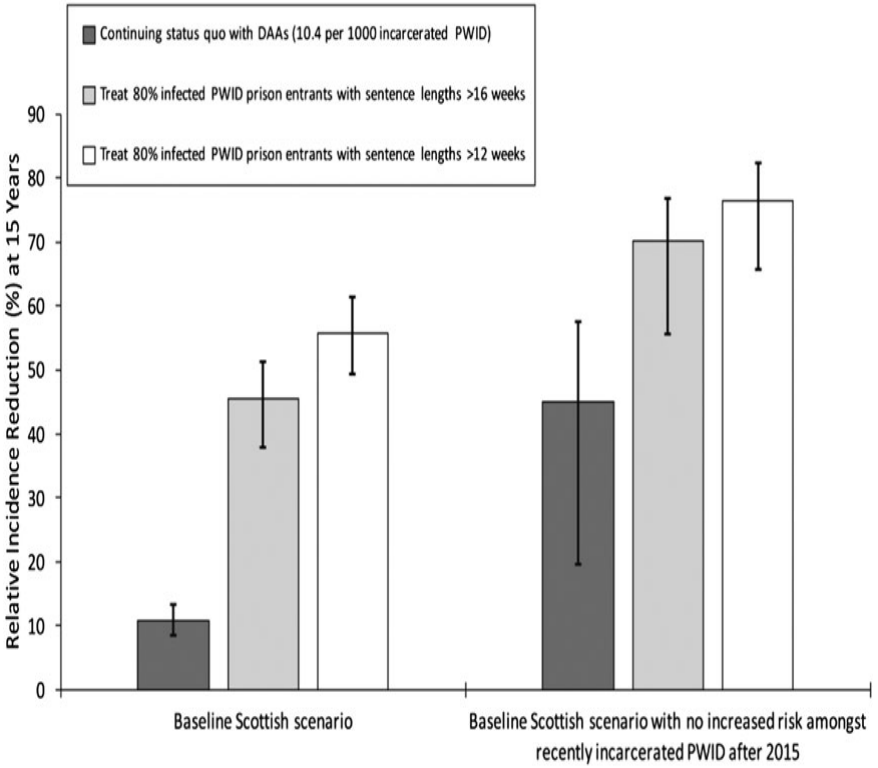
In the next 15 years, status quo treatment rates

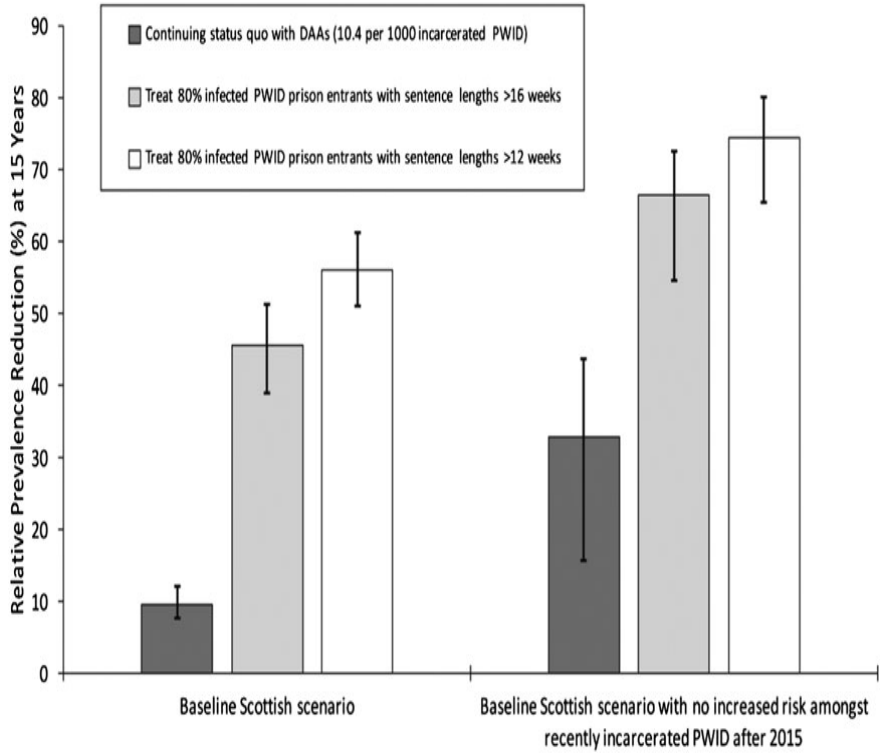
with / without existing prison **OST** could:

- reduce incidence by 10.7% / 3.1% and
- reduce chronic prevalence among all PWID by 9.7% /4.7%.

Stone J, et al. Addiction 2017; 112: 1302–14.

Modeling the impact of incarceration and prison-based HCV treatment on HCV transmission among PWID in Scotland



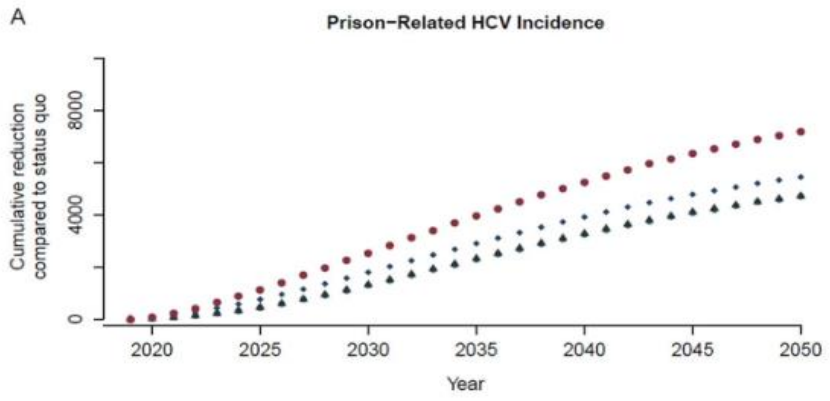


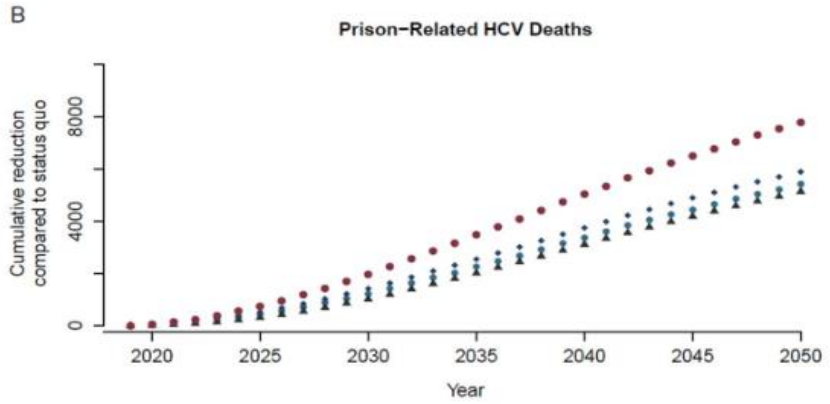
Period 2017-2032: scaling-up HCV treatments to 80% of chronic PWID prison entrants with sufficient sentences (>16 mths)

could reduce incidence by 45.6% and prevalence by 45.5%.

Stone J, et al. Addiction 2017; 112: 1302–14.

Modeling study:
Improved Health outcomes from HCV treatment Scale-Up in Spain's prisons





Treatment strategy	Treatment capacity	Treatment eligiblity: sentence length	Prioritization
● Strategy 1	2,000/year	≥ 6 months	Inmates by fibrosis stage
▲ Strategy 2	2,000/year	≥ 6 months	Prisons by HCV prevalence
◆ Strategy 3	Unlimited	≥ 6 months	None
● Strategy 4	Unlimited	Any	None

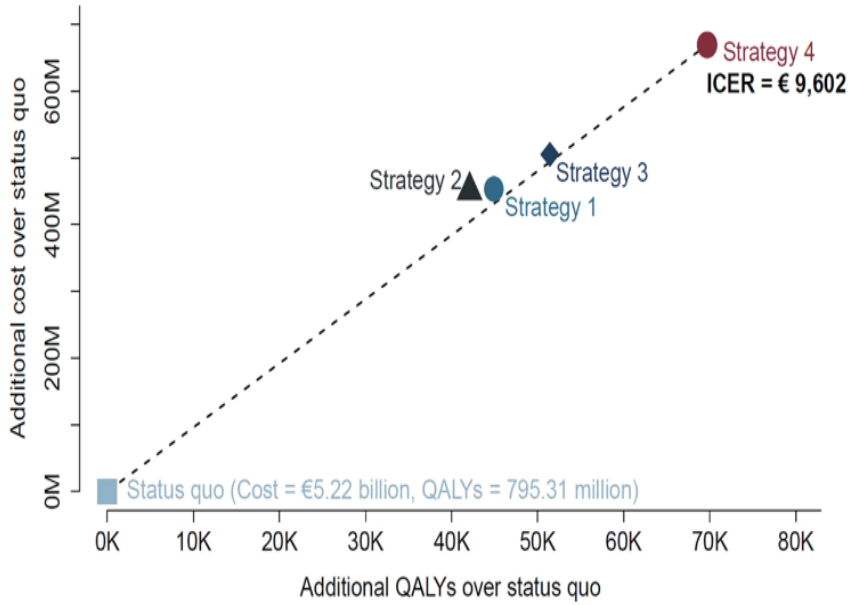
Period 2019-2050

Scaling-up treatment by treating **all** incarcerated persons provided maximum health benefits :

preventing 10,200 new HCV cases and **8,300 HCV-related deaths**

Dalgic OD, et al. ScientificRepoRtS 2019; 9:16849. https://doi.org/10.1038/s41598-019-52564-0

Modeling study
Improved Health outcomes from HCV treatment Scale-Up in Spain's prisons: A cost-Effectiveness Study



Treatment strategy	Treatment capacity	Treatment eligiblity: sentence length	Prioritization
Status quo	160/year	≥ 6 months	None
Strategy 1	2,000/year	≥ 6 months	Inmates by fibrosis stage
Strategy 2	2,000/year	≥ 6 months	Prisons by HCV prevalence
Strategy 3	Unlimited	≥ 6 months	None
Strategy 4	Unlimited	Any	None

Period 2019-2050

Compared to status-quo, scaling-up treatment by treating **all** incarcerated persons:

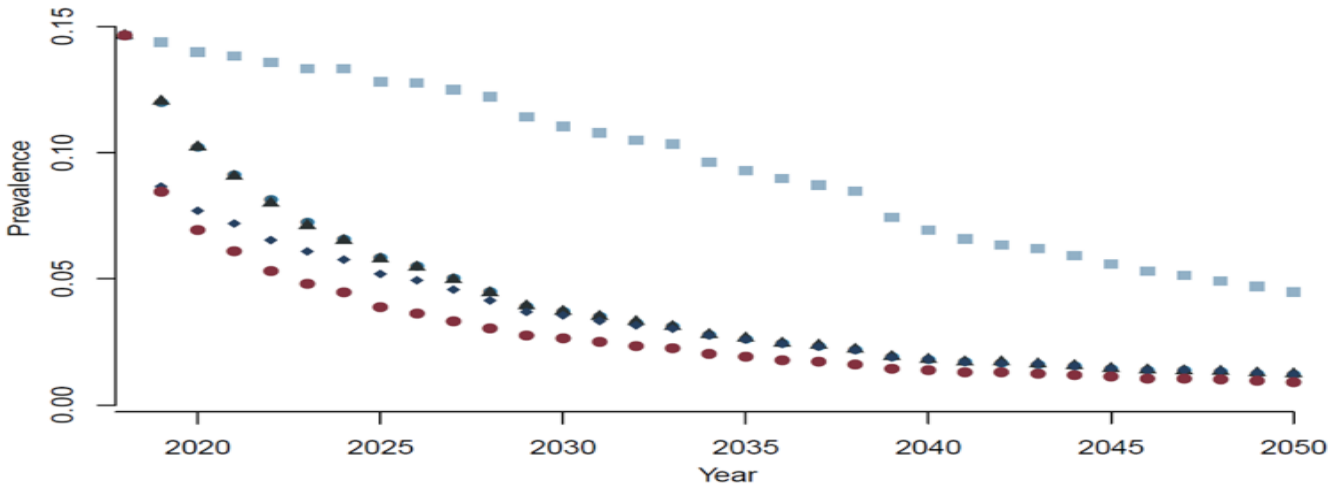
increased QALYs by 69,700
and
costs by EUR 6700 million

yielding an incremental **cost-effectiveness ratio** of EUR 9,600/QUALY

Dalgic OD, et al. ScientificRepoRtS 2019; 9:16849. https://doi.org/10.1038/s41598-019-52564-0

Modeling study

Improved Health outcomes from HCV treatment Scale-Up in Spain's prisons: A cost-Effectiveness Study



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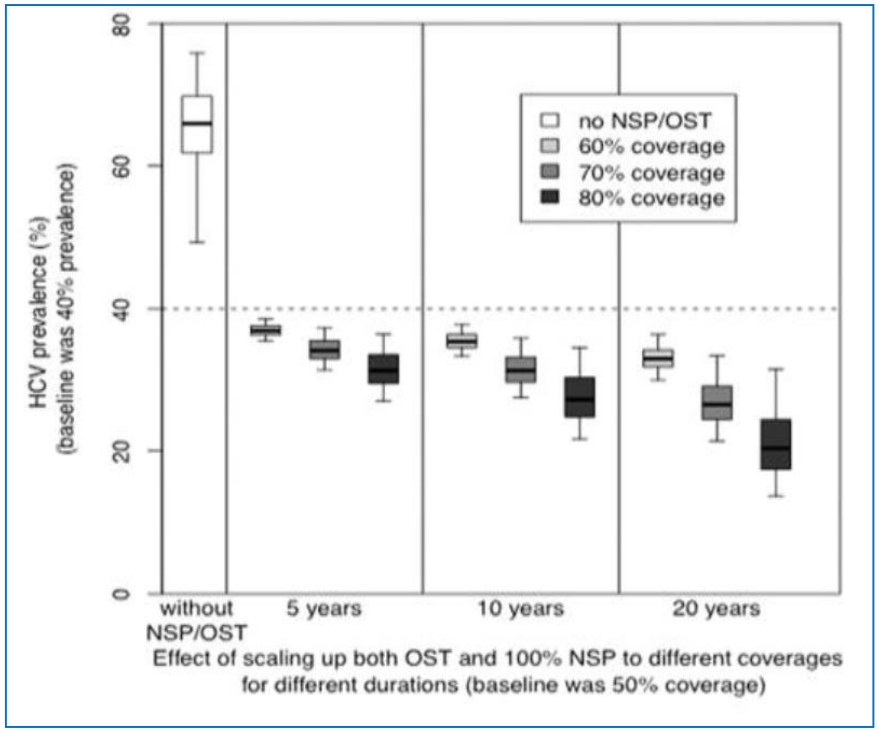
Strategy 3	Unlimited	≥ 6 months	None
Strategy 4	Unlimited	Any	None

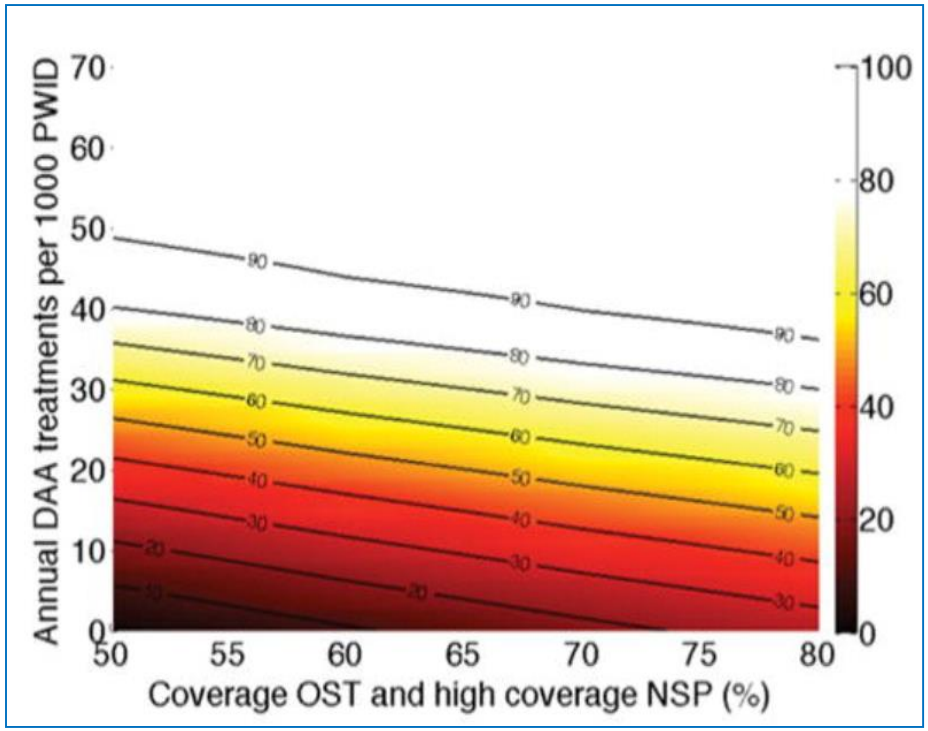
Scaling-up DAA tretment for the entire Spanish prison population, irrespective of sentence length,

is cost-effective and would reduce HCV burden

Dalgic OD, et al. ScientificRepoRtS 2019; 9:16849. https://doi.org/10.1038/s41598-019-52564-0

Modeling combination HCV prevention among PWID in the UK

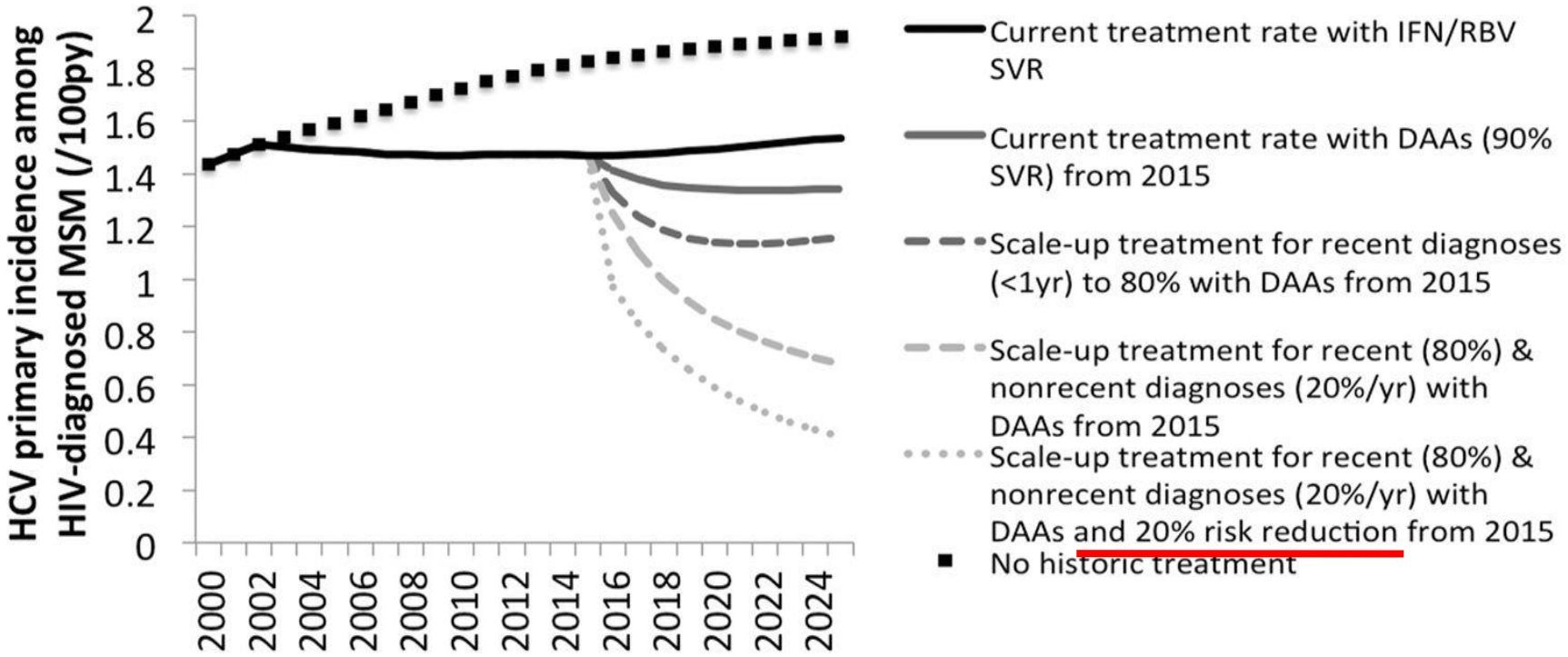




Modeling projections of the combined effects of harm reduction alone (A) and combination harm reduction and HCV DAA therapy (B) on HCV prevalence among PWID in the UK

*Martin NK, et al. AIDS Rev **2017** ; 19(2): 97–104.*

Modeling combination HCV prevention amon HIV-infected MSM in the UK

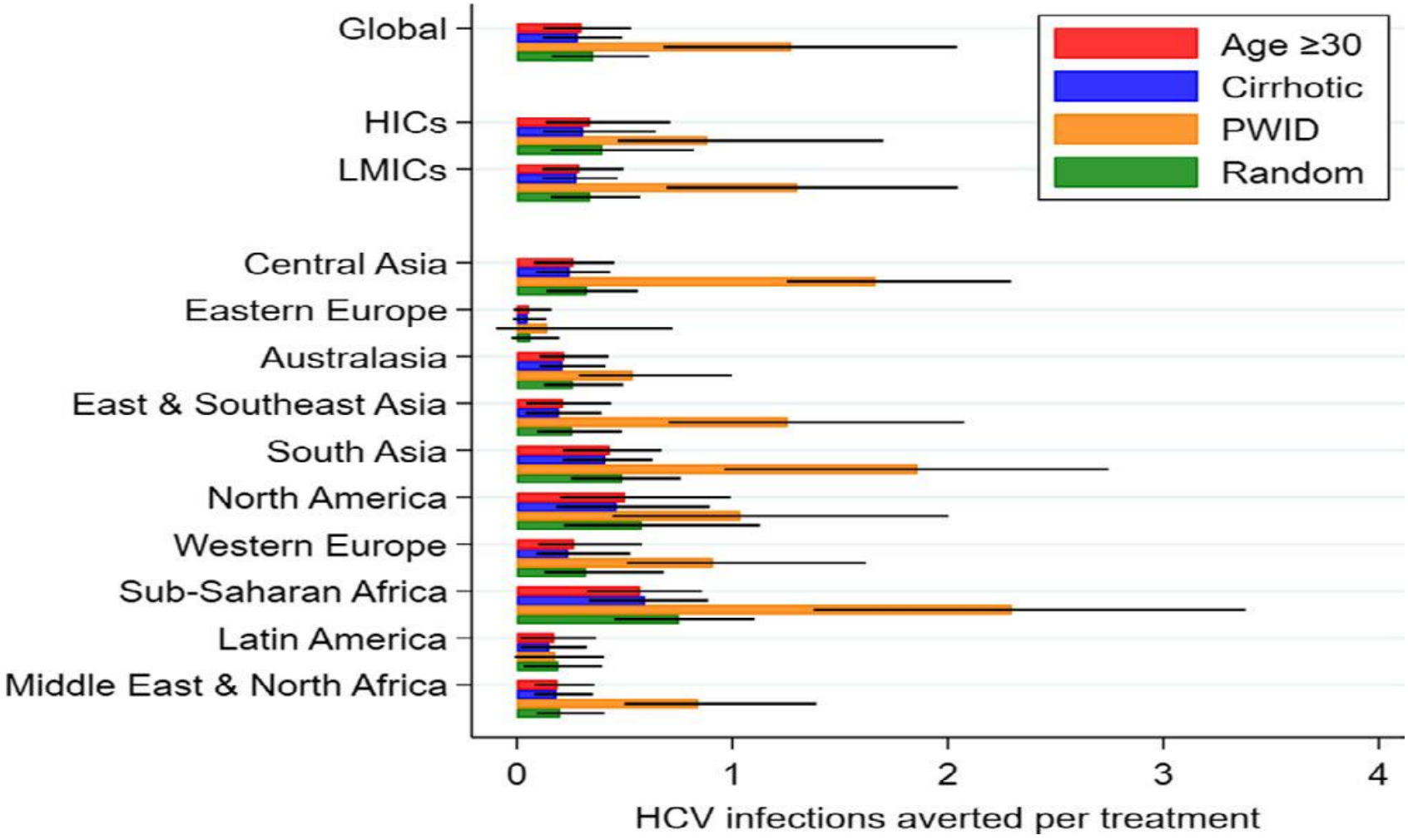


Modeling projections of the combined effects DAAs and behavior change interventions on HCV incidence among HIV-infected MSM in the UK

*Martin NK, et al. AIDS Rev **2017** ; 19(2): 97–104.*

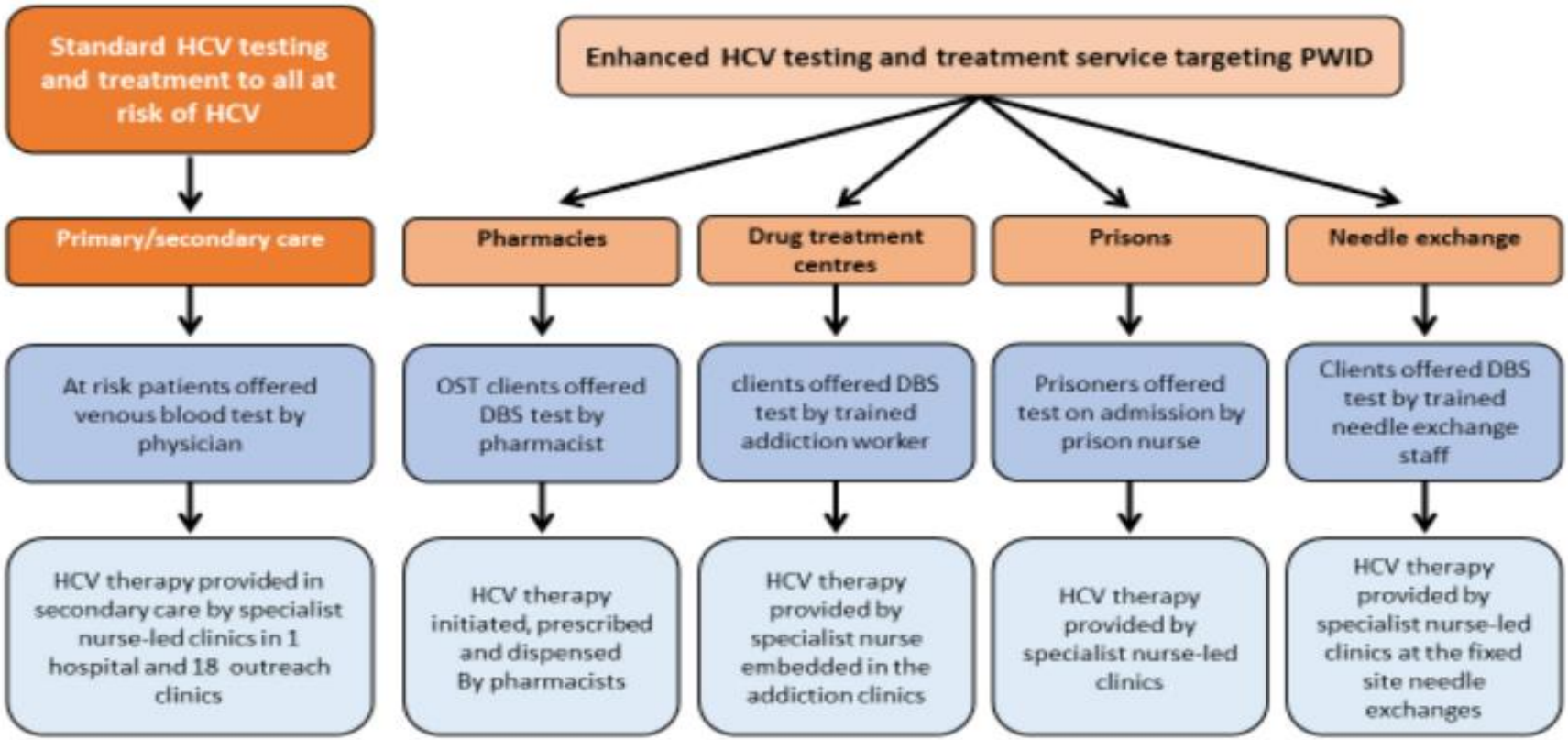
A modeling study

Modeling the potential prevention benefits of a treat-all HCV treatment strategy at global, regional and country levels



*Trickey A, et al. J Viral Hepat **2019**;26:1388–1403.*

A natural experiment
Evaluating the population impact of TAP for PWID (EPIToPe)



Overview of HCV testing and treatment pathways for the PWID population in NHS Tayside

Hickman M, et al. BMJ Open 2019;9:e029538. doi:10.1136/bmjopen-2019-0295

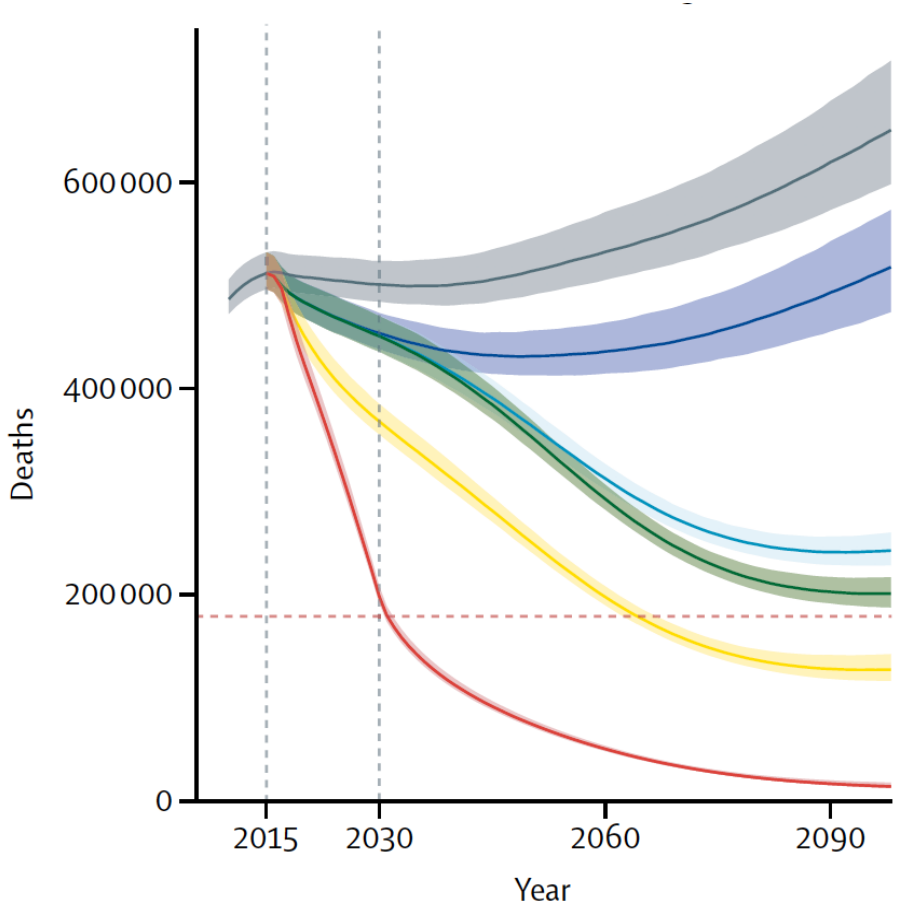
HCV treatment as prevention (TAP)

- Are DAAs effective on the **public-health level?**

Modeling studies and real-life studies:
TREATMENT WORKS AS PREVENTION

A global mathematical model
Scaling up prevention, testing and treatment towards the elimination of hepatitis C:

Global intervention results



No DAA - **Status quo** scenarios

Blood safety and infection control –
interventions reduce mortality in long term

PWID harm reduction
DAAs at the time of diagnosis –
improves long-term outlook

HCV testing / treatment scale-up

*Heffernan A, Lancet **2019**; 393: 1319-29.*

EASL Clinical Practice Guidelines 2020:
Treatment of hepatitis C

EASL. EASL recommendations on treatment of hepatitis C: Final update of the series. J Hepatol; XX: 1-49. In press.

EASL Clinical Practice Guidelines 2020: **Treatment of hepatitis C**

Indications for treatment: who should be treated?

All treatment-naïve and treatment-experienced patients with recently acquired or chronic HCV infection should be treated without delay.

Urgent treatment must be considered in patients with significant fibrosis (METAVIR score F2 or F3) or cirrhosis (METAVIR score F4), including decompensated cirrhosis; patients with clinically significant extrahepatic manifestations (*e.g.* symptomatic vasculitis associated with HCV-related mixed cryoglobulinaemia, HCV immune complex-related nephropathy and non-Hodgkin B cell lymphoma); patients with HCV recurrence after liver transplantation; patients at risk of a rapid evolution of liver disease because of concurrent comorbidities (non-liver solid organ or stem cell transplant recipients, HBV and human immunodeficiency virus [HIV] coinfections, diabetes); and individuals at high risk of transmitting HCV (people who inject drugs [PWIDs], men who have sex with men with high-risk sexual practices, women of childbearing age who wish to get pregnant, patients on haemodialysis, incarcerated individuals). PWIDs and men who have sex with men with high-risk sexual practices should be made aware of the risk and routes of reinfection and transmission and should apply preventive measures after successful treatment.

EASL. EASL recommendations on treatment of hepatitis C: Final update of the series. J Hepatol 2020; XX: 1-49. In press.

EASL Clinical Practice Guidelines 2020:
Treatment of hepatitis C, PWID

- All PWIDs who are infected with HCV, including those receiving OST, those with a history of injecting drug use and those who recently injected drugs, should be treated according to the general recommendations **(A1)**.

- Following SVR, monitoring for HCV reinfection through bi-annual or, at least, annual HCV RNA assessment should be undertaken in PWIDs with an ongoing risk behaviour

- Retreatment should be made available if reinfection is identified during post-SVR follow-up **(A1)**.

- HCV treatment should be scaled-up in PWIDs to increase the likelihood of achieving the goals of HCV elimination in this group of patients, including treatment as prevention **(A1)**.

EASL. EASL recommendations on treatment of hepatitis C: Final update of the series. J Hepatol 2020; XX: 1-49. In press.

EASL Clinical Practice Guidelines 2020:
Treatment of hepatitis C, prisoners

Recommendations

- Opt-out screening for HCV infection should be offered to all incarcerated individuals **(A1)**.
- HCV treatment should be offered to all incarcerated individuals with chronic hepatitis C, following the above general recommendations **(A1)**.
- OST should be made available to all opiate-dependent incarcerated individuals **(B1)**.
- Needle-syringe exchange programmes acceptable to incarcerated individuals and prison staff should be available in prisons **(B1)**.

EASL. EASL recommendations on treatment of hepatitis C: Final update of the series. J Hepatol 2020; XX: 1-49. In press.

Eliminating Hepatitis C – An Action Plan

Globally, there are an estimated 71 million people actively infected with HCV, and 11-14 million of these reside in Europe

EASL Recommends:

1. Increasing awareness amongst HCPs, patients, policy-makers, the media and the public (especially high risk groups), whilst combating the stigma and discrimination that is associated with HCV infection
2. Implementing harm reduction strategies, such as access to opioid substitution therapy, safe injecting equipment for drug users and safe sex education
3. Making DAAs available at reasonable prices, to avoid any further reimbursement restrictions and to allow governments to implement a comprehensive elimination strategy
4. Improving access to treatment and care by increasing the number of authorised prescribers, promoting telemedicine and by increasing input from AHPs during and after treatment
5. Treating every Hepatitis C patient at the earliest opportunity, especially those at high risk
6. Providing rapid testing, in all relevant settings, with priority given to high-risk persons

EASL/ILC 2019. Vienna, April 14, 2019.

EASL
The Home of Hepatology

POLICY STATEMENT

Drug use and the global hepatitis C elimination goal

A time for change - EASL call to action

In order to achieve the 2030 WHO viral hepatitis elimination goals, EASL recommends:

that all barriers to the uptake of healthcare services by PWID be removed by changing policies and discrimination that hinder access. This includes the decriminalisation of minor, non-violent drug offences and the adoption of an approach based on public health promotion, respect for human rights and evidence.

www.easl.eu

EASL/ILC 2020. Digital, August 27, 2020.

Decriminalisation of drug use in the context of HCV elimination

The decriminalisation of the consumption, purchase and possession of or personal consumption of plants, substances or preparations, not exceeding the amount for individual consumption during a certain period of time.

Such decriminalisation of personal consumption restores the right to health and social reintegration of a drug user.

However, decriminalisation by itself brings about **only a reduction in punishment and not a public health response**.

EASL/ILC 2020. Digital, August 27, 2020.

To eliminate HCV in PWID, combining activities is required

Decriminalization of personal drug possession and consumption

Integrated interventions (HCV testing, counseling and treatment)

PWID can freely access centres of assistance regardless of their drug consumption

EASL/ILC 2020. Digital, August 27, 2020.

CONCLUSIONS

- HCV treatment with DAAs made the strategy of TAP feasible
- Modeling studies confirm that TAP works in all risk groups: PWID, MSM, prisoners, PLWH
- Real-life studies showed that TAP worked in the studied cohorts of the particular risk groups as well as outside the studies
- Other preventive and harm-reduction strategies need to accompany TAP

Question

Recommendations for TAP:

- For risk-groups? All?

- Include TAP in the viral hepatitis prevetion guidelines – aside other preventive and harm-reduction measures?

Medicine Nobel 2020 honors three scientists for discoveries on hepatitis C virus