Hepatitis C Elimination

Strategies to enhance hepatitis C care and treatment in people who inject drugs

Margaret Hellard

Burnet Institute, Melbourne

Alfred Hospital, Melboure

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Disclosures

- I receive fellowship support from the National Health and Medical Research Council (Australia).
- The Burnet Institute receives infrastructure support from the Victorian Government Operational Infrastructure Fund.
- Gilead Science
- Abbvie
- BMS

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Overview of today's presentation

- Overview of hepatitis C and WHO elimination targets
- The new medications – direct acting antivirals
- Why Australia can eliminate hepatitis C
- What we need to do to eliminate hepatitis C - including strategies to increase access to care by PWID

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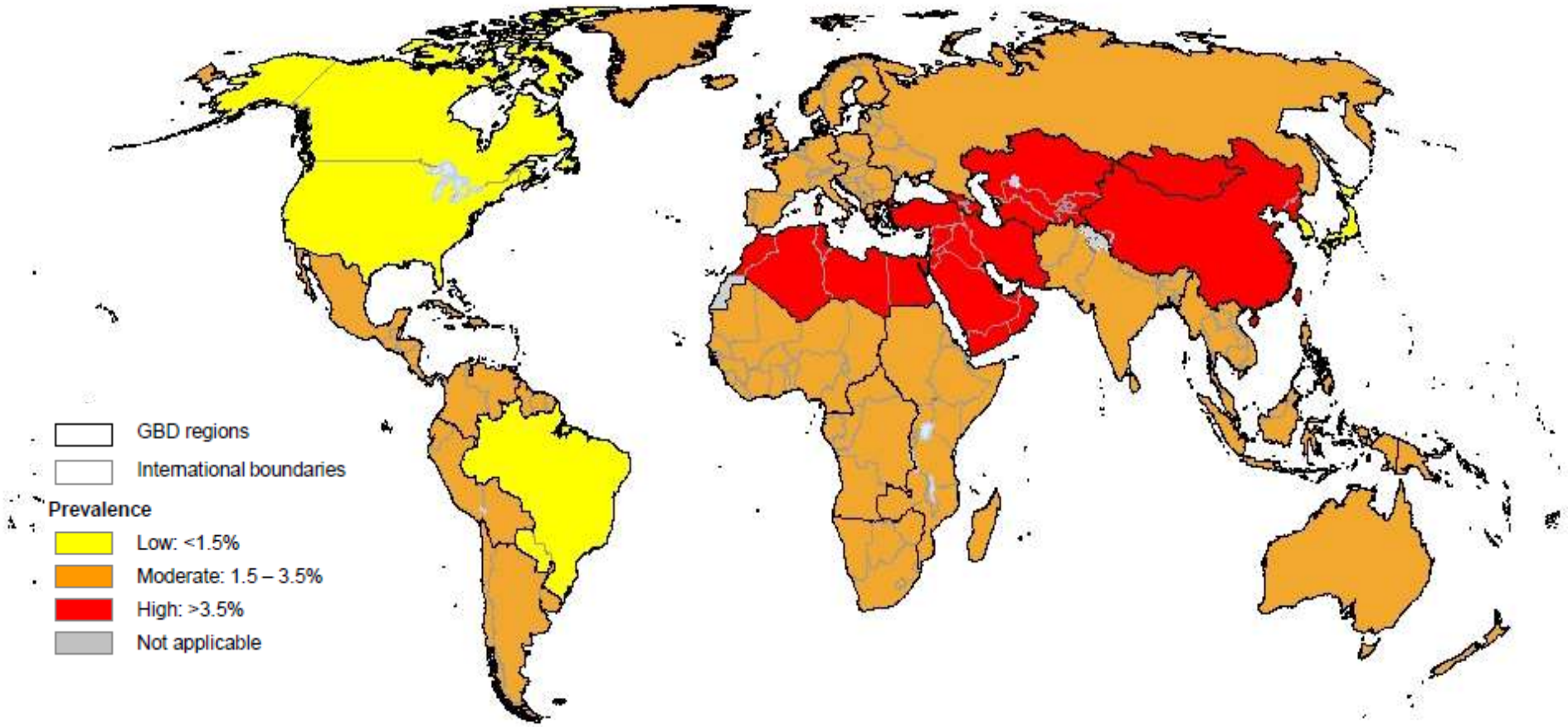
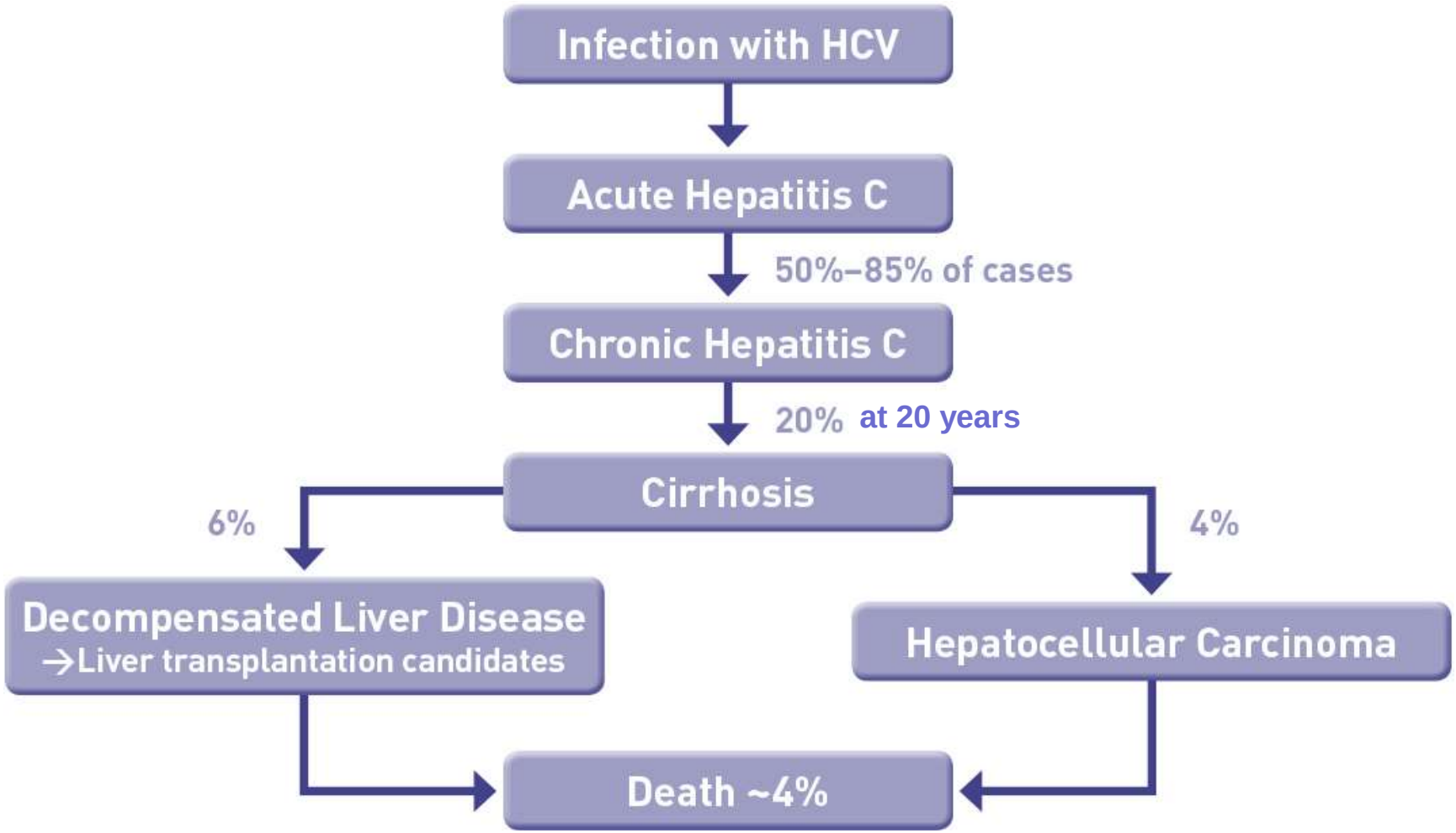
Global prevalence of hepatitis C infection, 2005 adults (19-49 years), by GBD region



Estimated that 110 – 130 million persons with chronic hepatitis C

Source: Hannafiah et al. Hepatology 2013

Natural history



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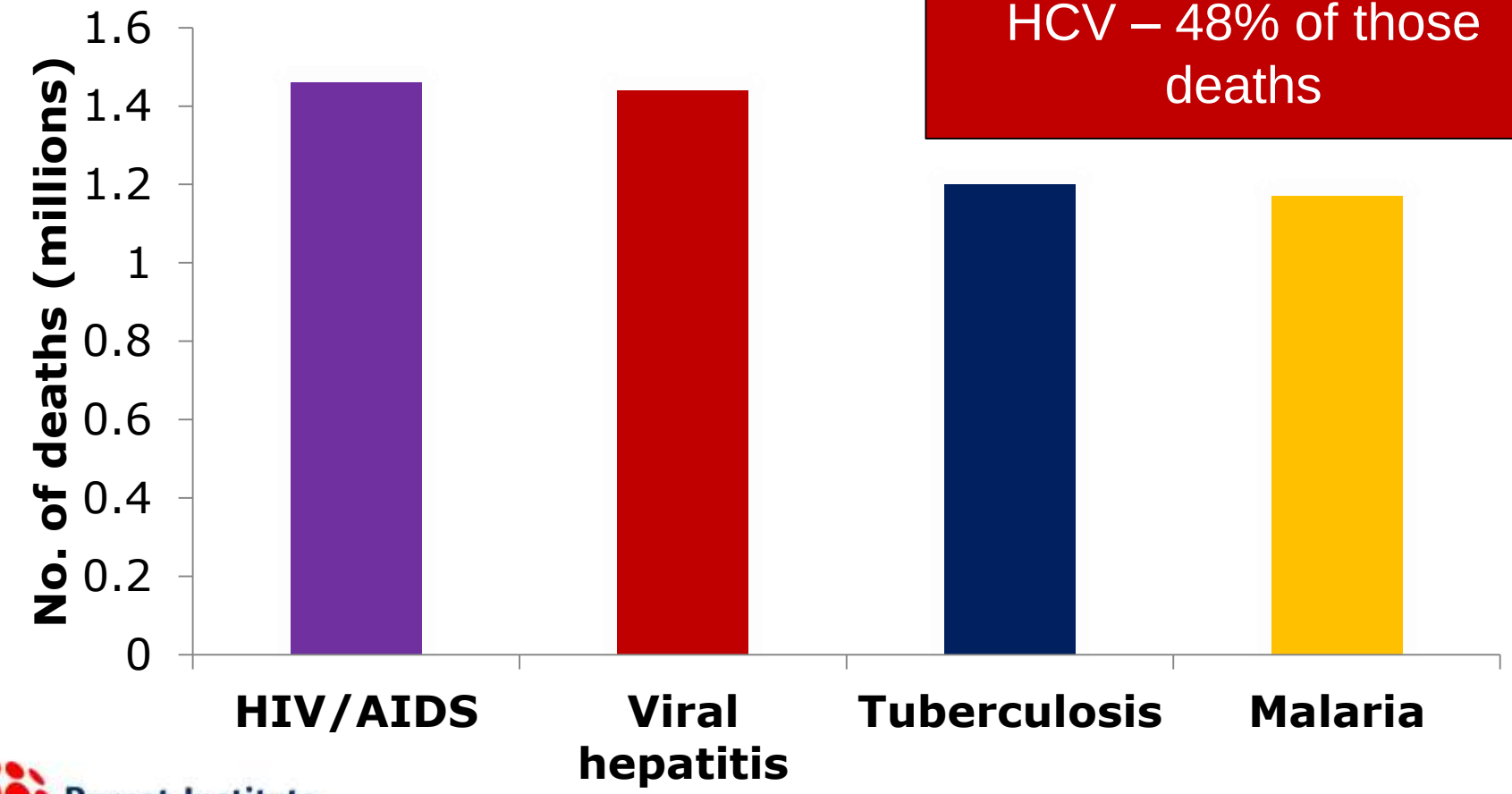
Reference: Bisceglie AM. Natural History of Hepatitis C: Its Impact on Clinical Management. Hepatology 2000; 31(4): 1014-018.

Number of deaths/year from selected conditions, 2010

1.4 million people died in 2010 of viral hepatitis HCV – 48% of those deaths



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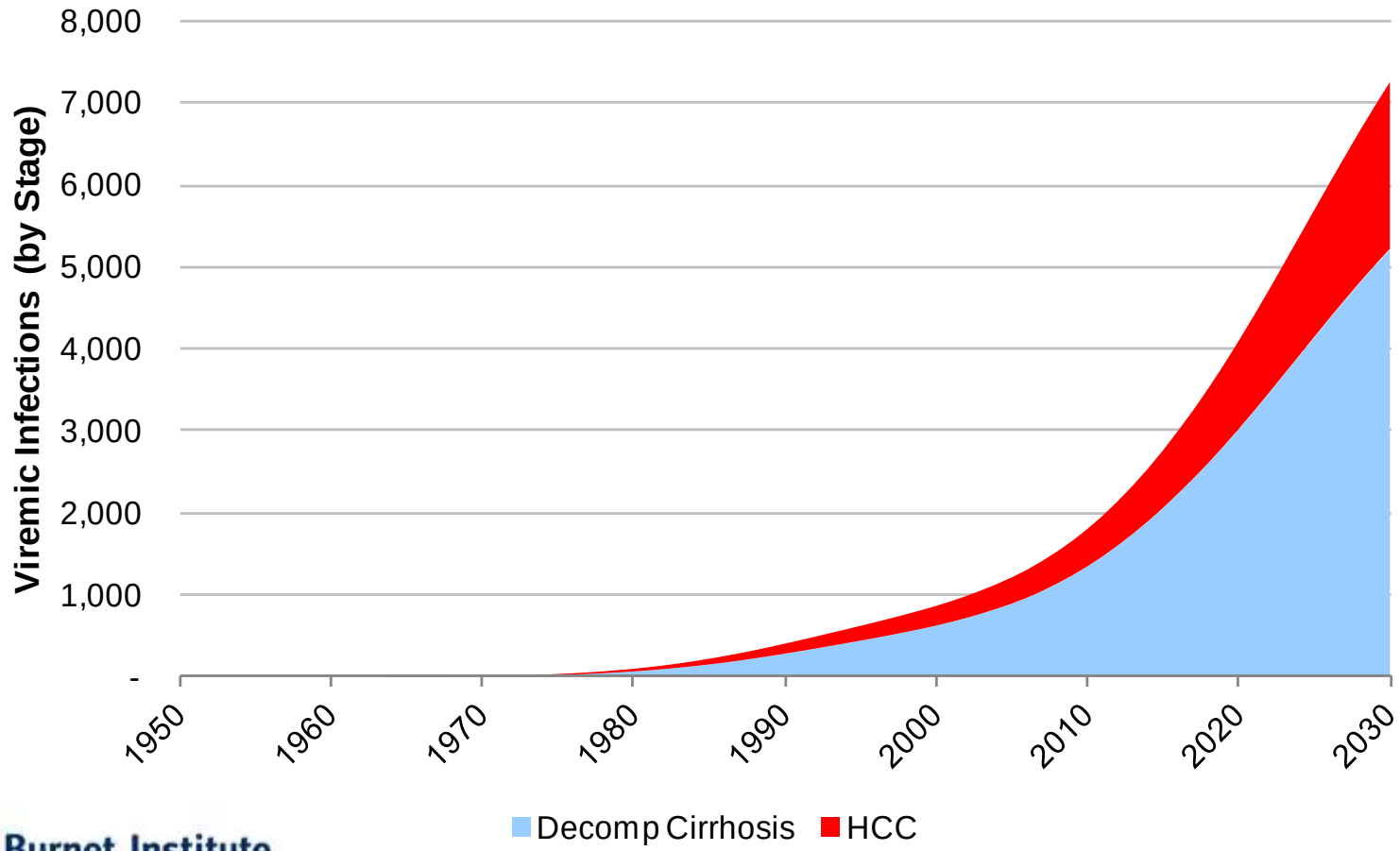
Source: Global Burden of Disease Study 2010 Lozano et al, Lancet 2012

Chronic HCV liver disease burden

Estimates and projections of DC and HCC in Australia



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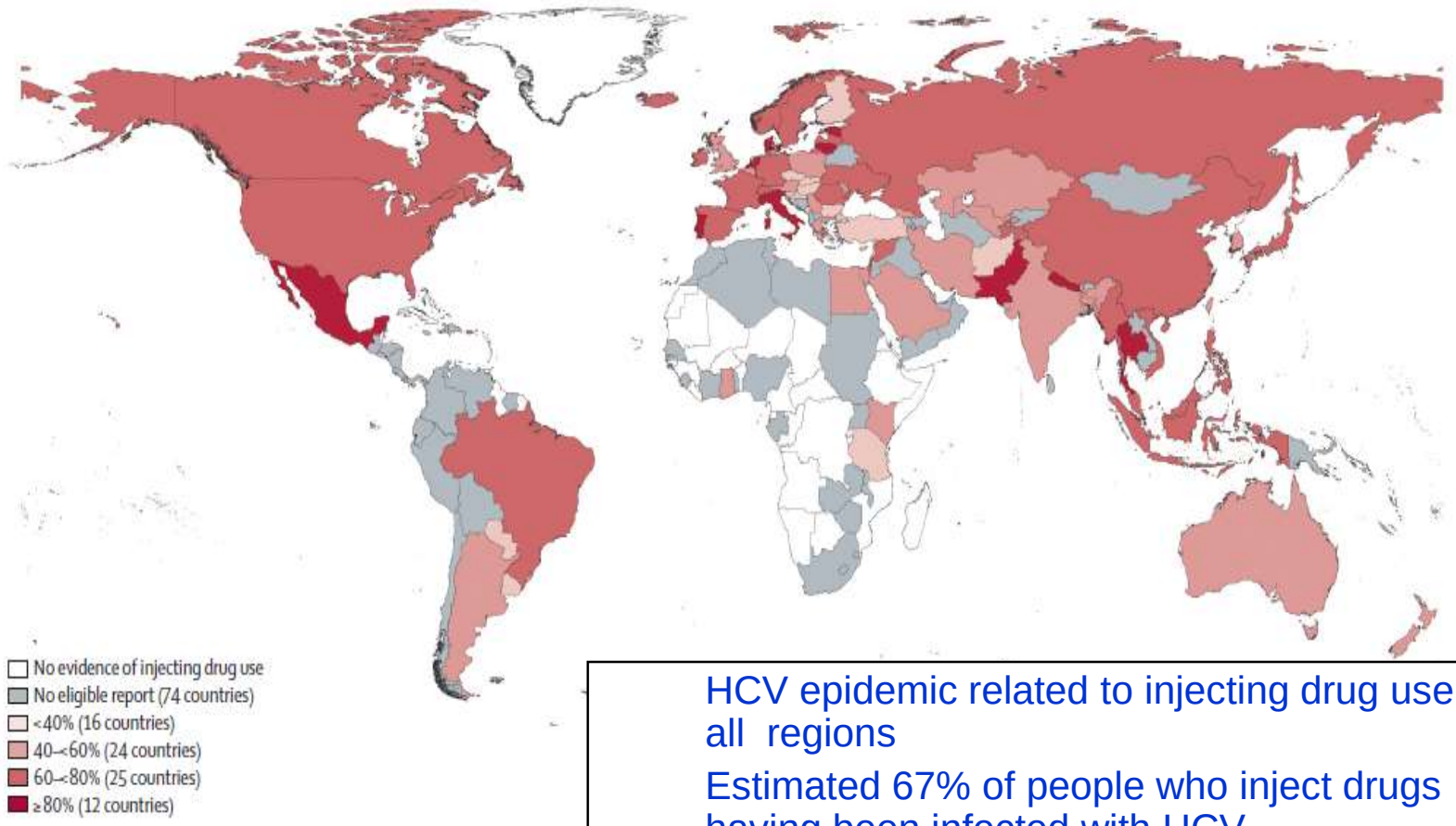
Sievert W et al. JGH 2014

Prevalence of HCV among persons who inject drugs



HCV epidemic related to injecting drug use – all regions

Estimated 67% of people who inject drugs having been infected with HCV.

Nelson et al. Global epidemiology of hepatitis B and hepatitis C in people who inject drugs: results of systematic reviews. Lancet, 378 (9791), 2011.

Post-2015 Development Agenda

Sustainable Development Goals (SDGs)

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

- 3.3 By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and **combat hepatitis,** water-borne diseases and other communicable diseases

Universal health coverage - another key component of the SDGs - achieved when all people receive the health services they need, which are of sufficient quality to make a difference, without those people incurring financial hardship.

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WHO

Vision:

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

Goal:

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

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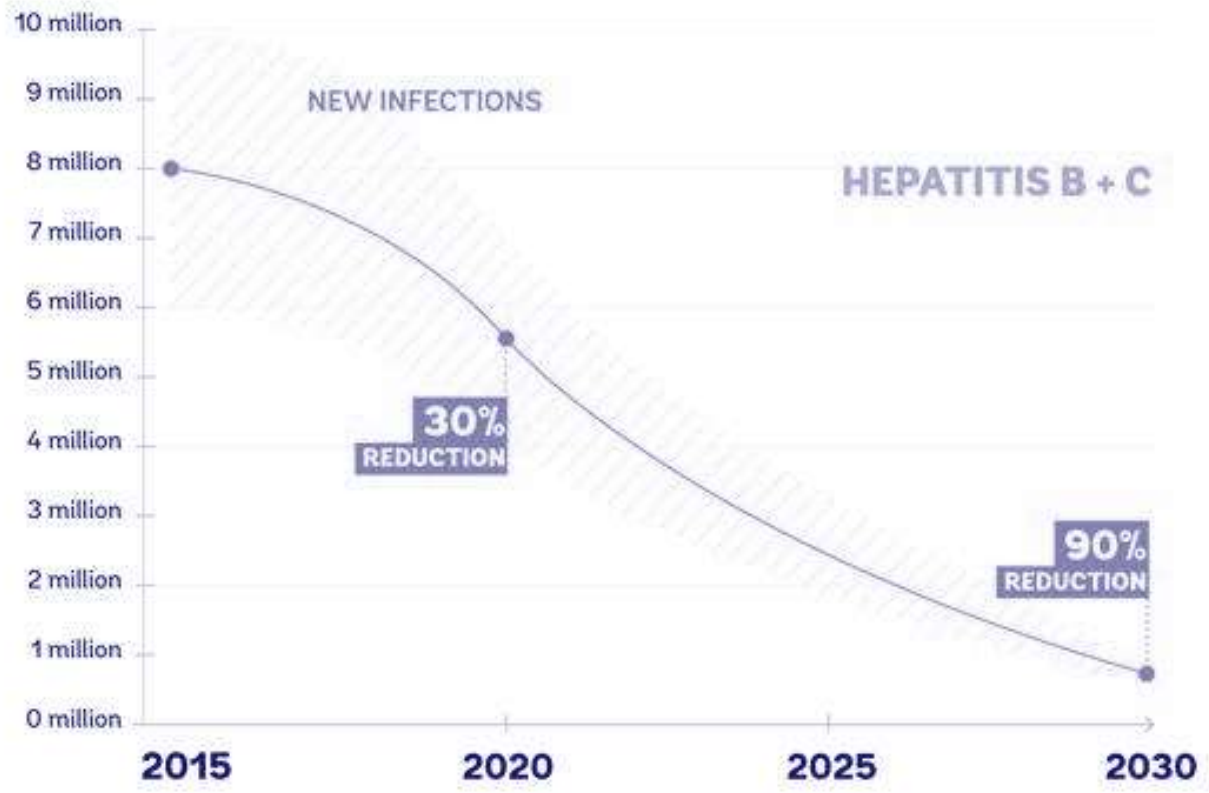
PROPOSED GLOBAL TARGETS FOR VIRAL HEPATITIS



New cases of chronic HCV infections - 80% decline

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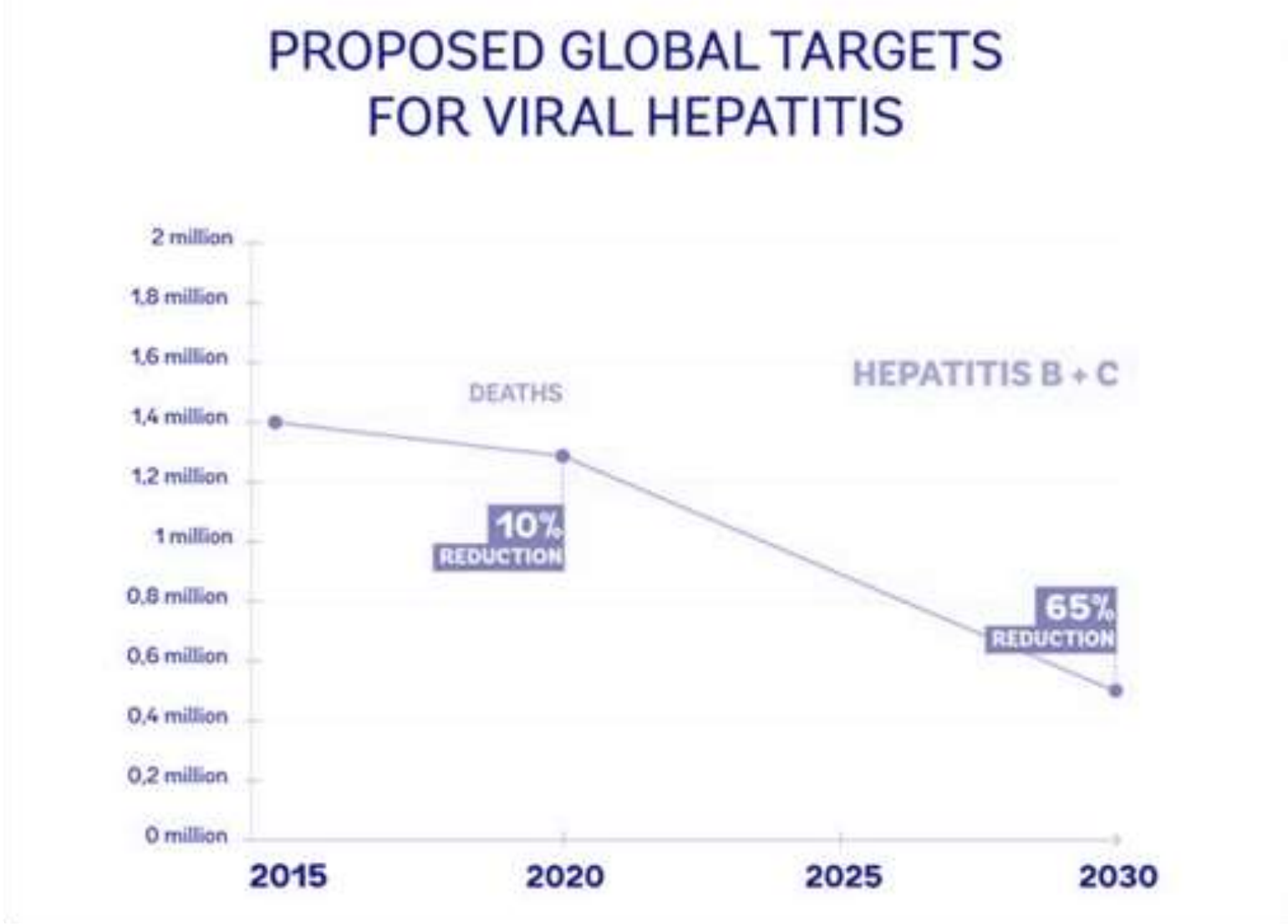

Hepatitis C deaths – 65% reduction

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Achieving the 2030 targets

Diagnosis

- 90% of chronic infections diagnosed

Treatment

- 80% of eligible persons with chronic HCV treated

Harm reduction

- Number of sterile needles and syringes provided per person who injects drugs per year - increase from 20 to 300. Estimated to be 75% coverage
- I can't see a specific number for increasing coverage for opioid substitution therapy

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Direct acting antivirals

Simpler, safer and more effective

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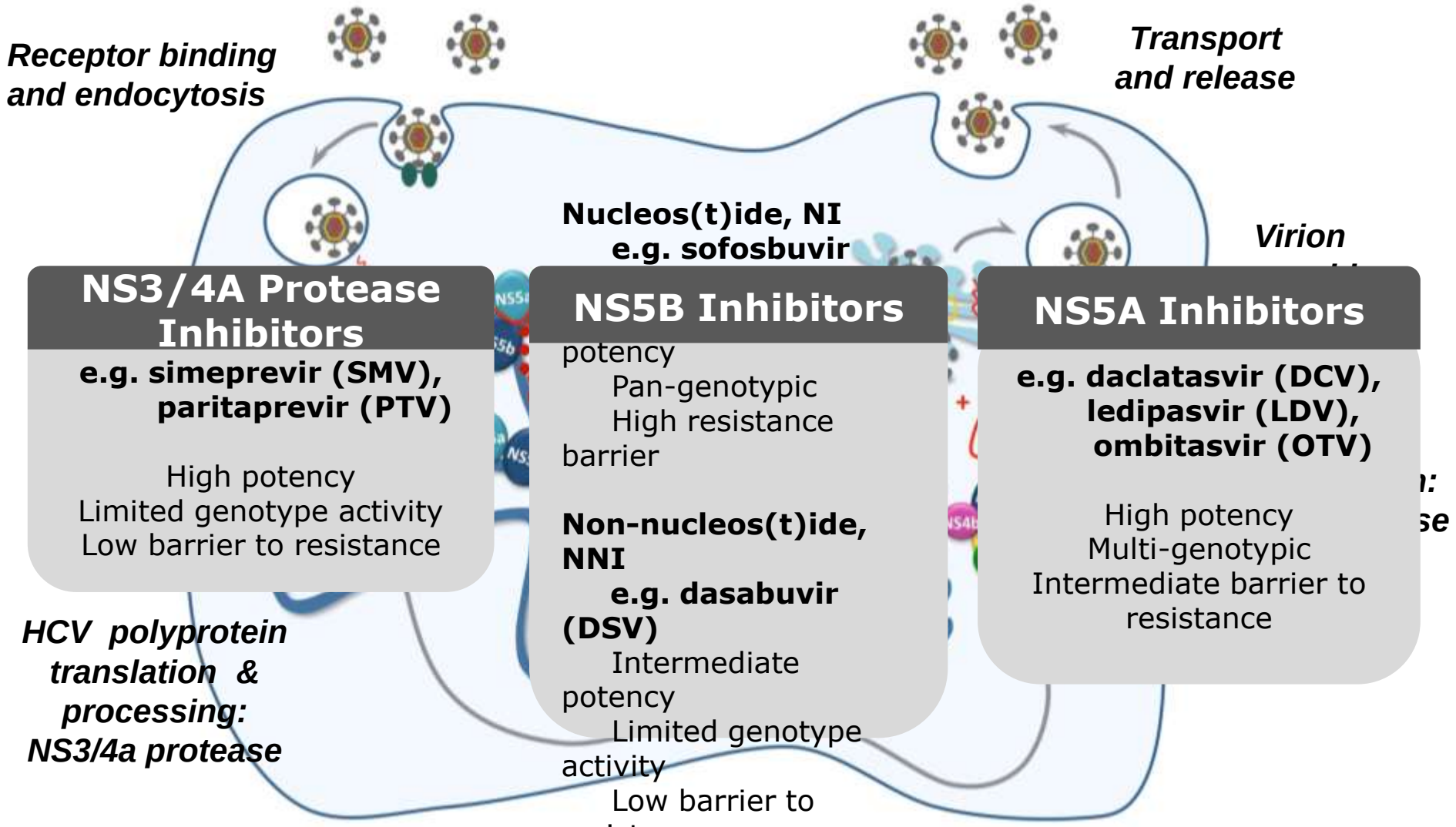
HCV Life cycle: targets for DAAs



The very big news!


NEWS

LOCATION: Melbourne, Vic Change

Just In | Australia | World | Business | Sport | Analysis & Opinion | Fact Check

Federal Government to spend $1 billion on groundbreaking Hepatitis C treatments

By political reporter Jane Norman

Updated 20 Dec 2015, 4:33pm

- Available through PBS from 1 March 2016
  - Through both PBS General Schedule (Section 85) and Section 100 Highly Specialised Drugs Program

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New treatments

- The medicines listed on the PBS from 1 March 2016 are:
  - daclatasvir (Daklinza®)
  - ledipasvir with sofosbuvir (Harvoni®)
  - sofosbuvir (Sovaldi®) and ribavirin (Ibavyr®)

- The PBS listing for peginterferon alfa-2a (&) ribavirin (Pegasys RBV®) will also be amended to allow its use in combination with sofosbuvir

- Viekera Pak – recently listed

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Who can prescribe these new medicines?

- Specialist physicians (gastroenterologists, hepatologists or infectious disease physicians)
- GPs can prescribe these new medicines in, or following, consultation with a specialist physician experienced in treatment of chronic hepatitis C infection
  - i.e. a GP must consult with a specialist by phone, mail, email or videoconference prior to prescribing
- PBS Authority approval is required prior to prescribing
  - Contact Department of Human Services (Medicare)

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Who can access these new medicines?

- Accessible to **all** adult patients with chronic hepatitis C infection across all genotypes/severities
  - Treatment for each patient depends on patient's genotype, their cirrhotic status and if they had previously had treatment
  - Includes prisoners (funded by Government rather than state/territory)
- Patient must attend an appointment with a GP or specialist physician

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What is the cost for patients?

- Patients will pay no more than the relevant PBS co-payment at each dispensing of medicine
  - Up to $38.30 for most medicines/$6.20 with concession
  - Pharmacists may choose to discount

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Who can dispense these medicines?

- If a prescription is issued under the **S85** General Schedule, approved pharmacists in the community will be able to dispense these new medicines

- However, if a prescription has been written by a prescriber under the **S100** HSD arrangements in a public hospital, these prescriptions may only be dispensed by a section 94 approved hospital authority

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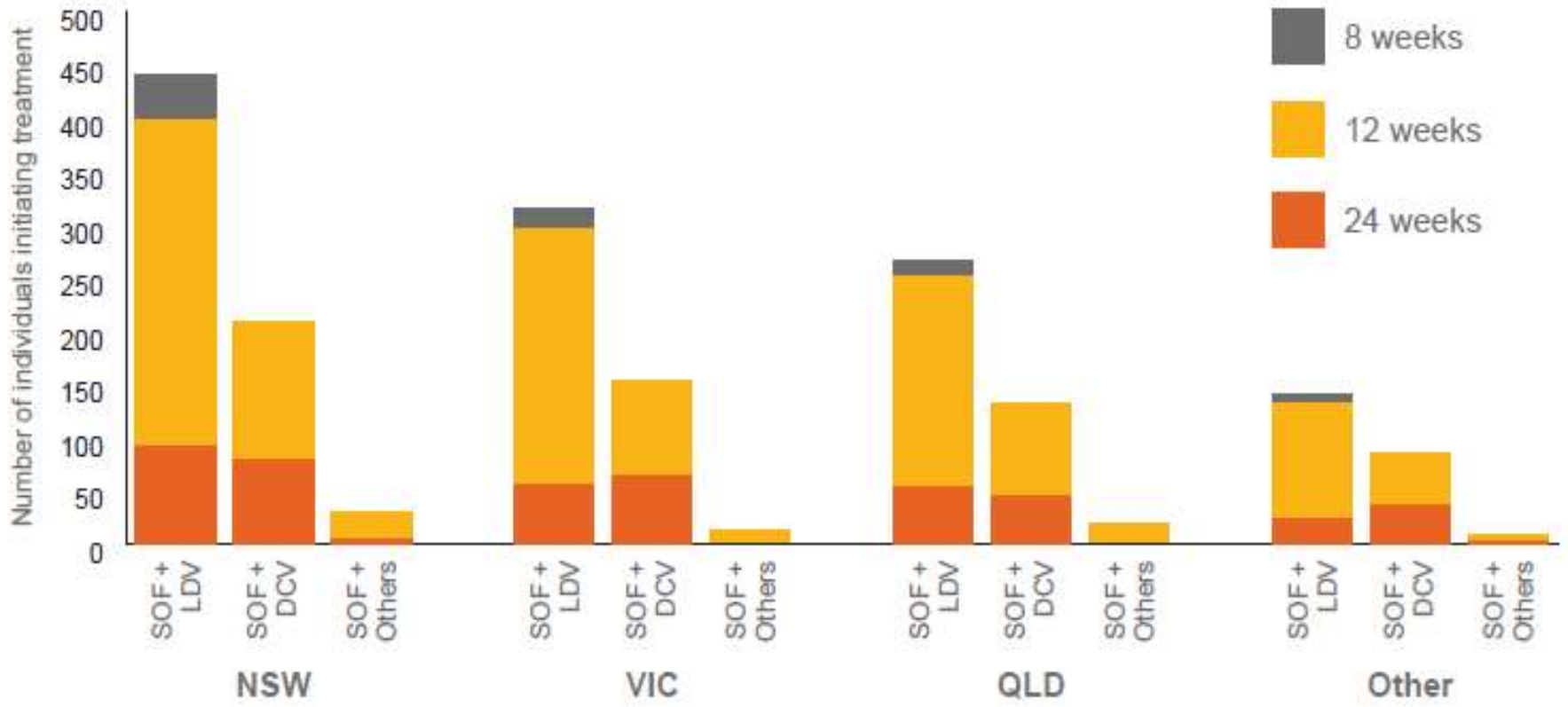
HCV treatment in Australia: March 2016 PBS



SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir ; NSW: New South Wales; VIC: Victoria; QLD: Queensland

Treatment works

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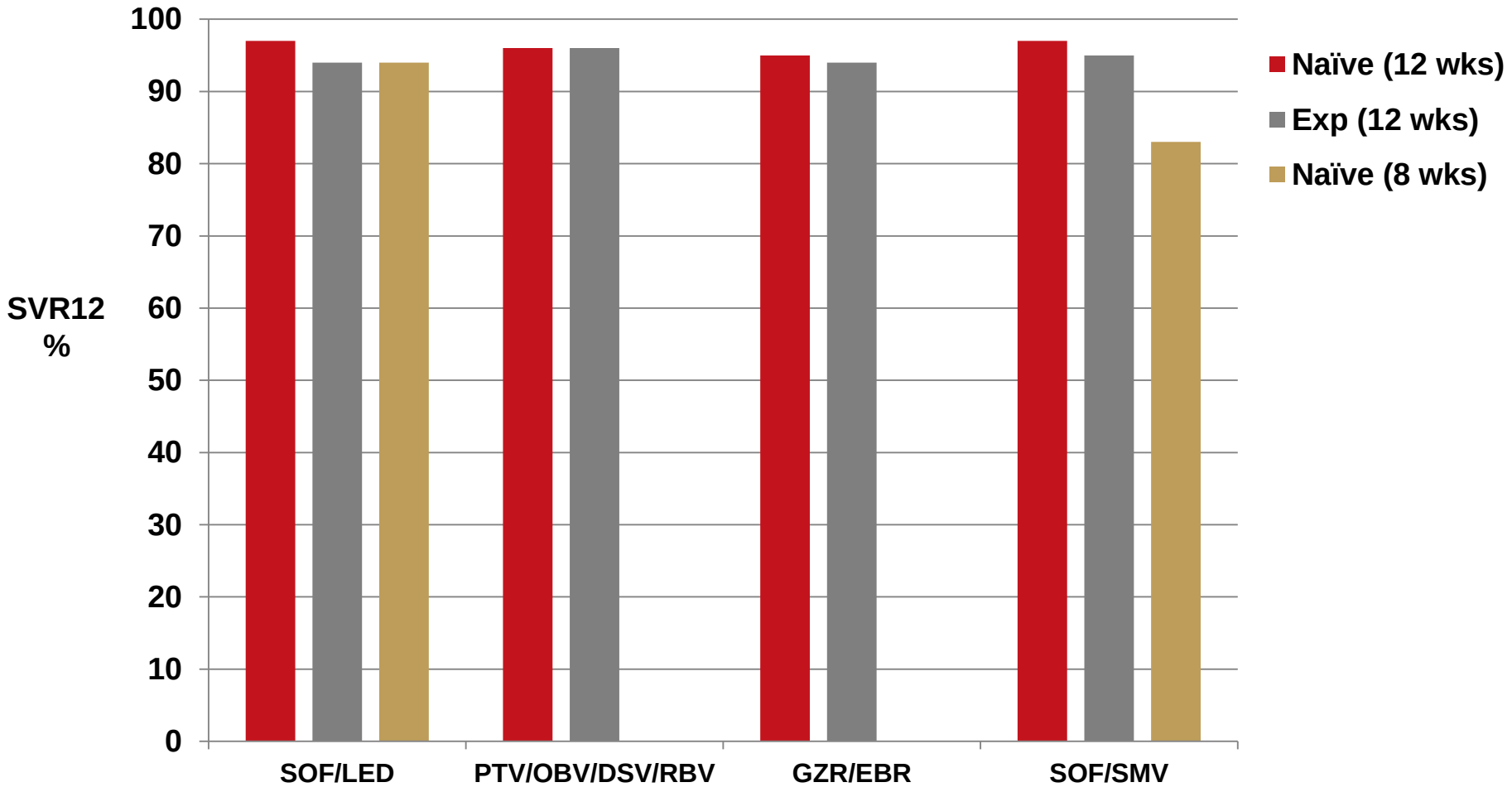
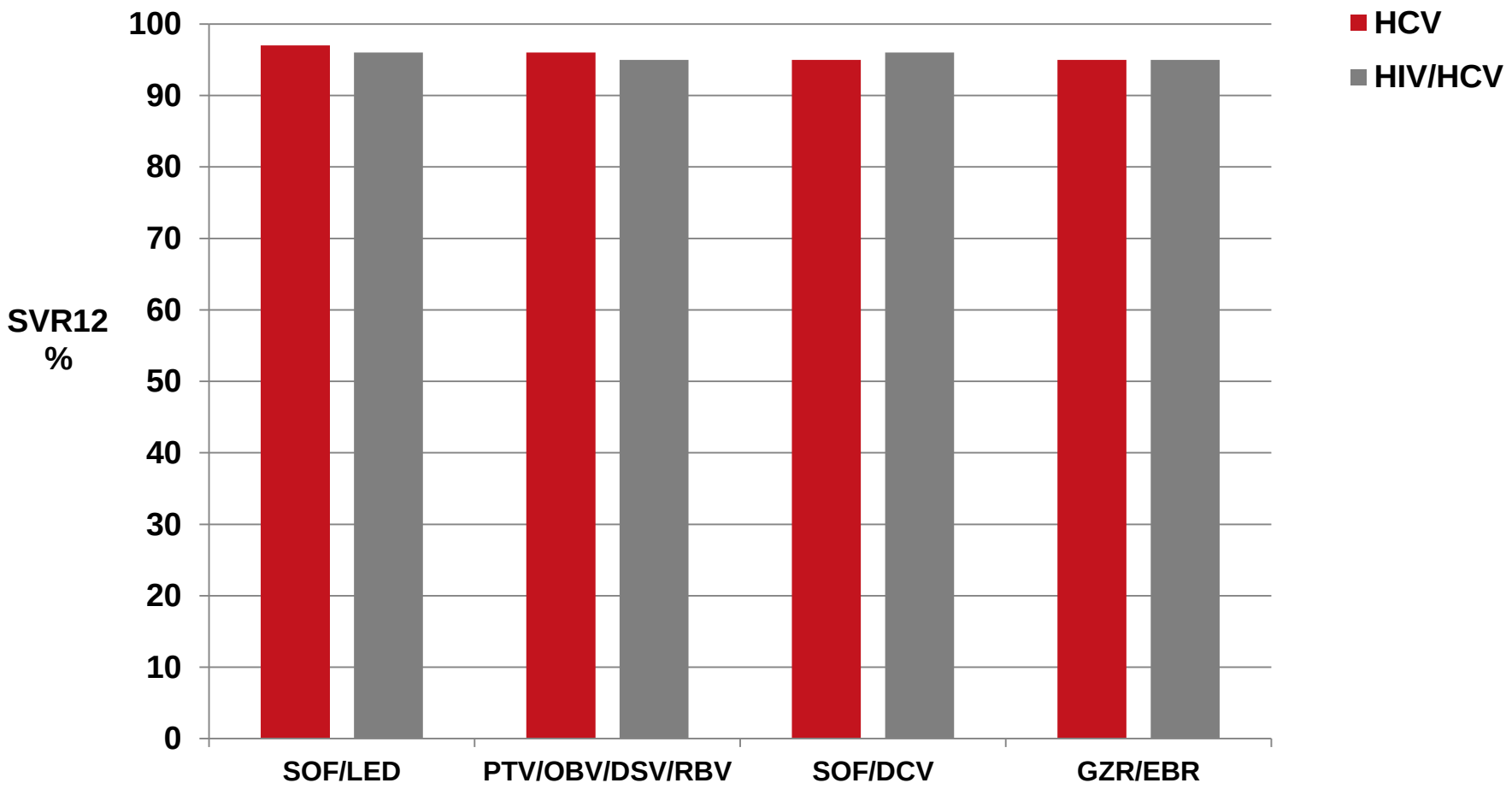
IFN-free DAA therapy: GT1 regimens



Zeuzem, NEJM 2014; Afdhal, NEJM 2014; Kowdley, NEJM 2014; Feld, NEJM 2014; Zeuzum, ILC 2015; Kwo, ILC 2015

IFN-free DAA therapy: HCV vs HIV/HCV

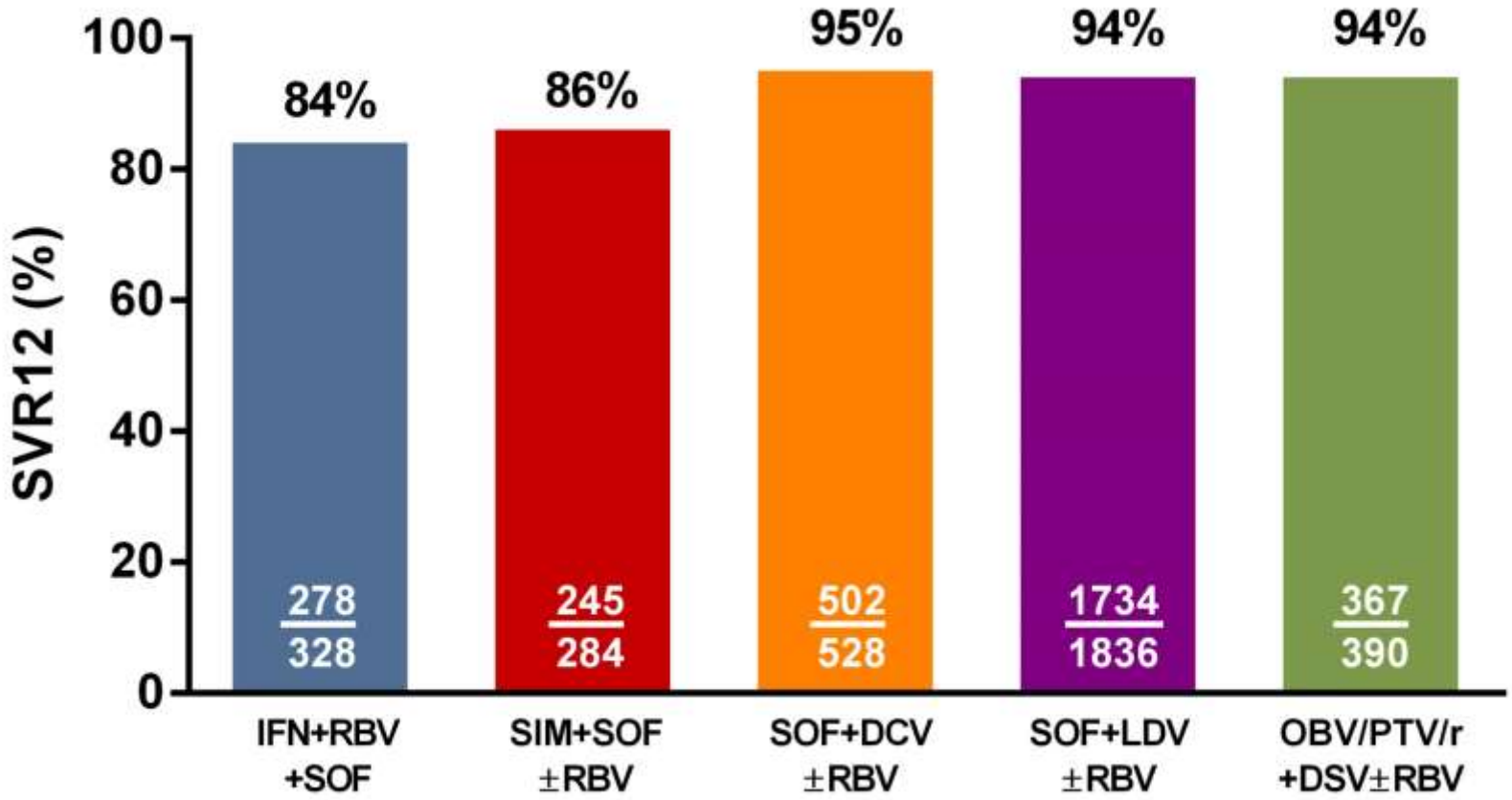
GT1, treatment naïve, F0-4; 12 weeks duration



Afdhal, NEJM2014; Naggie, CROI2015; Feld, NEJM2014; Rockstroh, WAC2014; Wyles, CROI2015; Zeuzem, ILC2015; Rockstroh, ILC2015; Poordad, ILC2015

Real world IFN-free DAA therapies - Germany

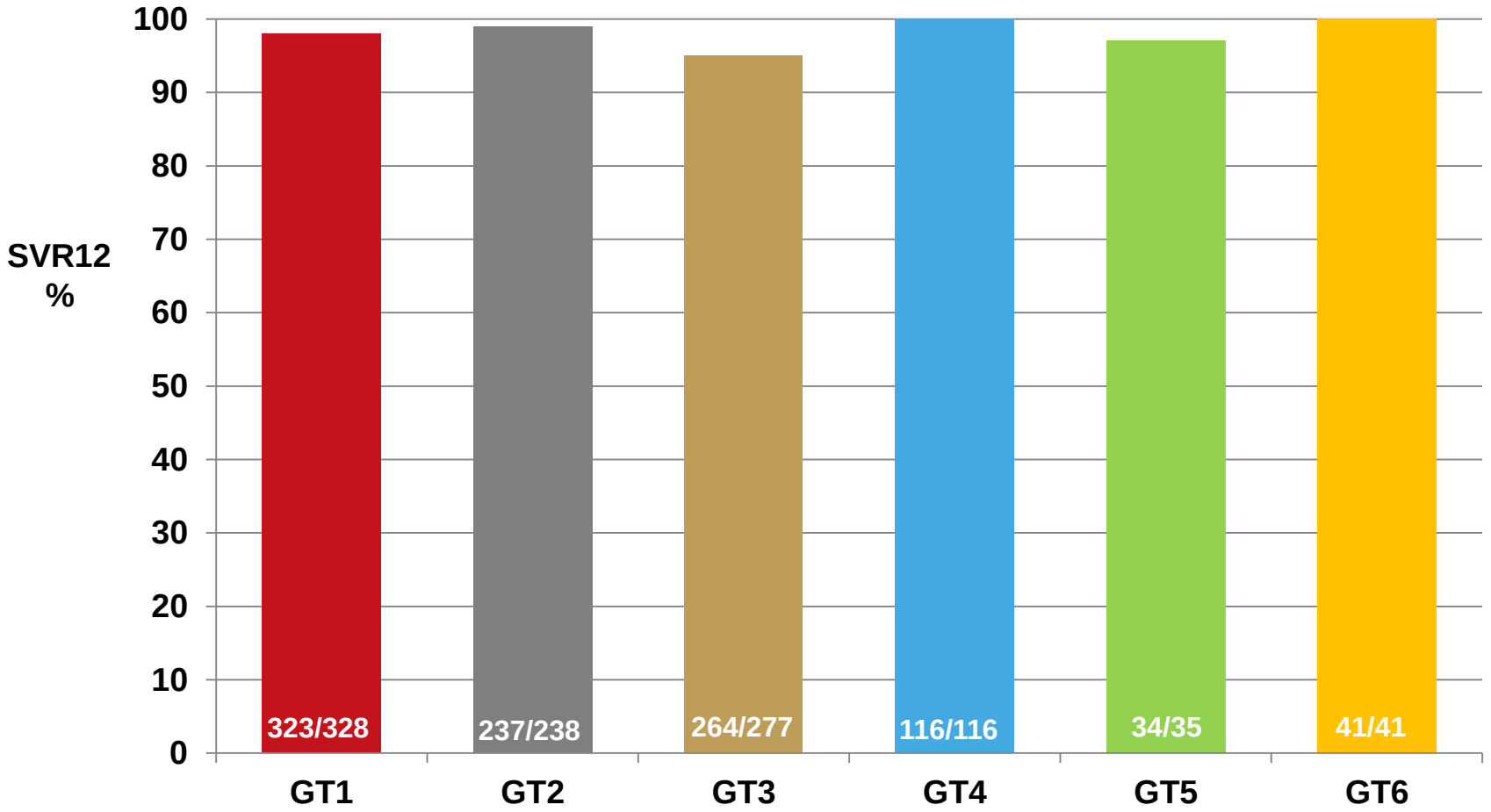
Genotype 1



Mauss ILC 2016 (SAT-263)

Sofosbuvir/Velpatasvir

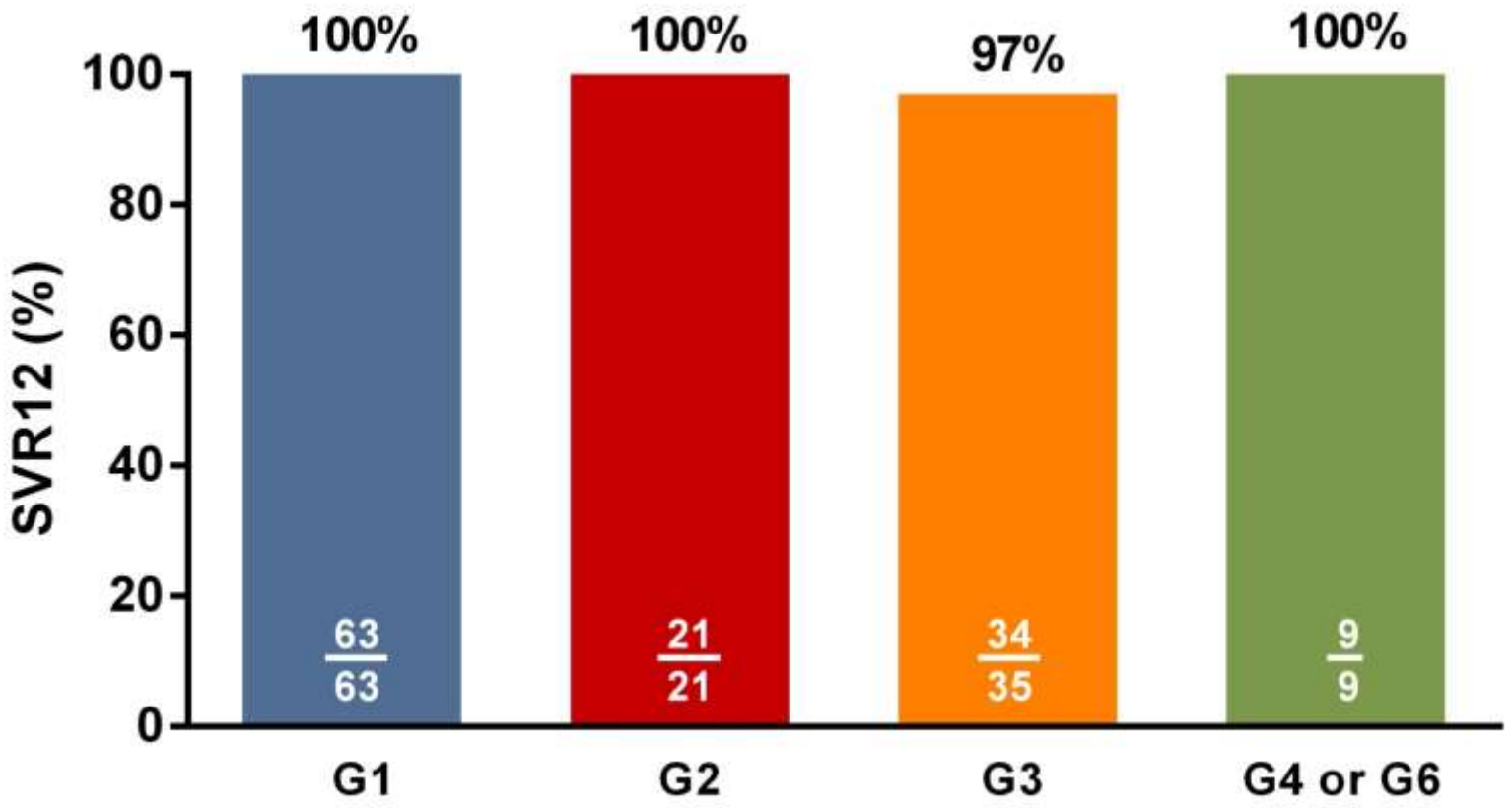
GT1-6, treatment naïve and exp. (28%), F0-4 (21% F4), 12 wks



Feld JJ, et al. NEJM 2015; Foster GR, et al. NEJM 2015

SOF/VEL/GS-9857 in treatment experienced

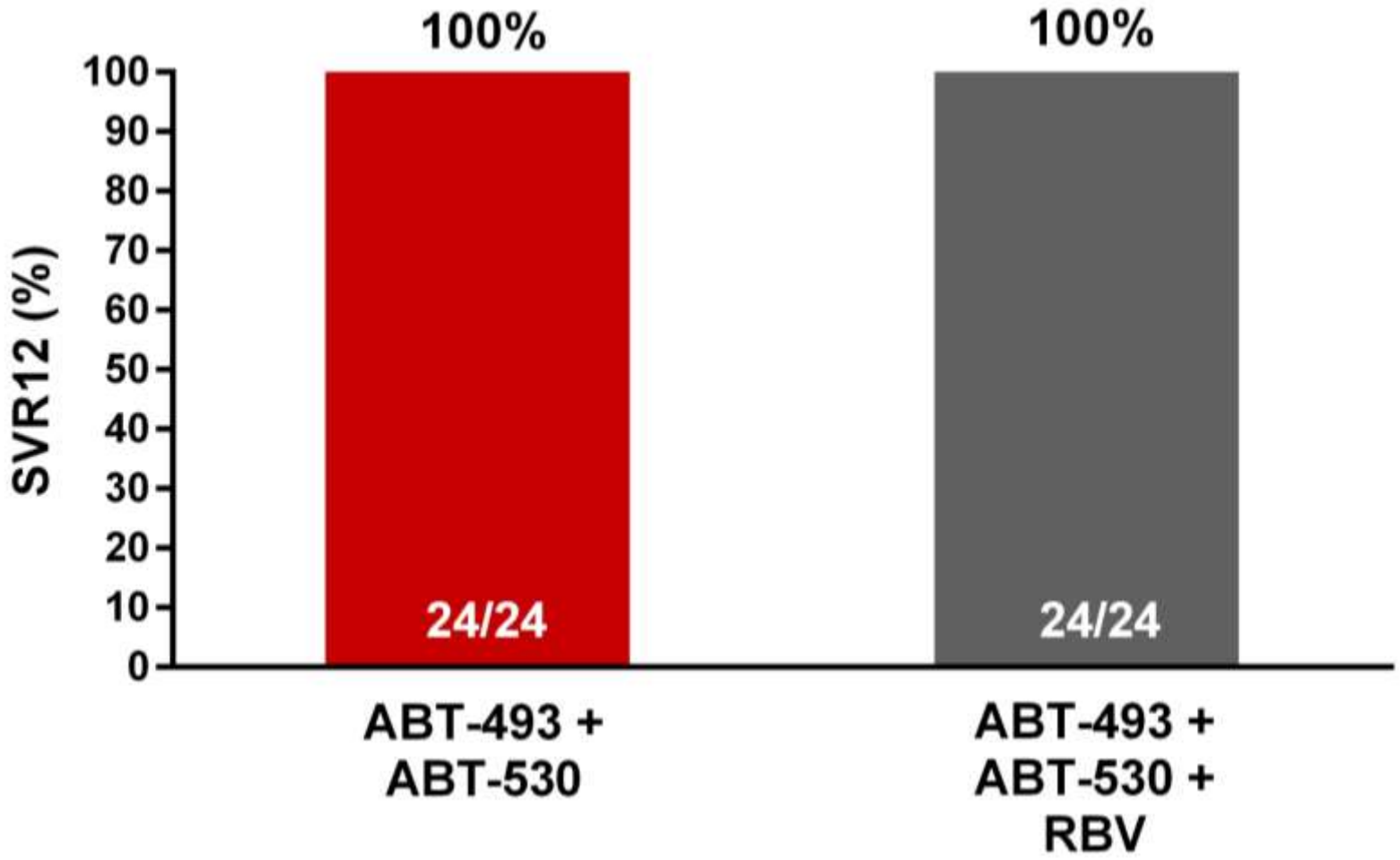
GT1-6; TE (NS5A-27%, non-NS5A-52%, no prev DAA-21%), 48% compensated cirrhosis, 12 weeks



Lawitz E, et al ILC 2016 (PS008)

ABT-493/ABT-530±RBV in G3 + cirrhosis

GT3; TN, compensated cirrhosis, 12 weeks



Kwo P, et al ILC 2016 (LB01)

Why Australia can eliminate HCV

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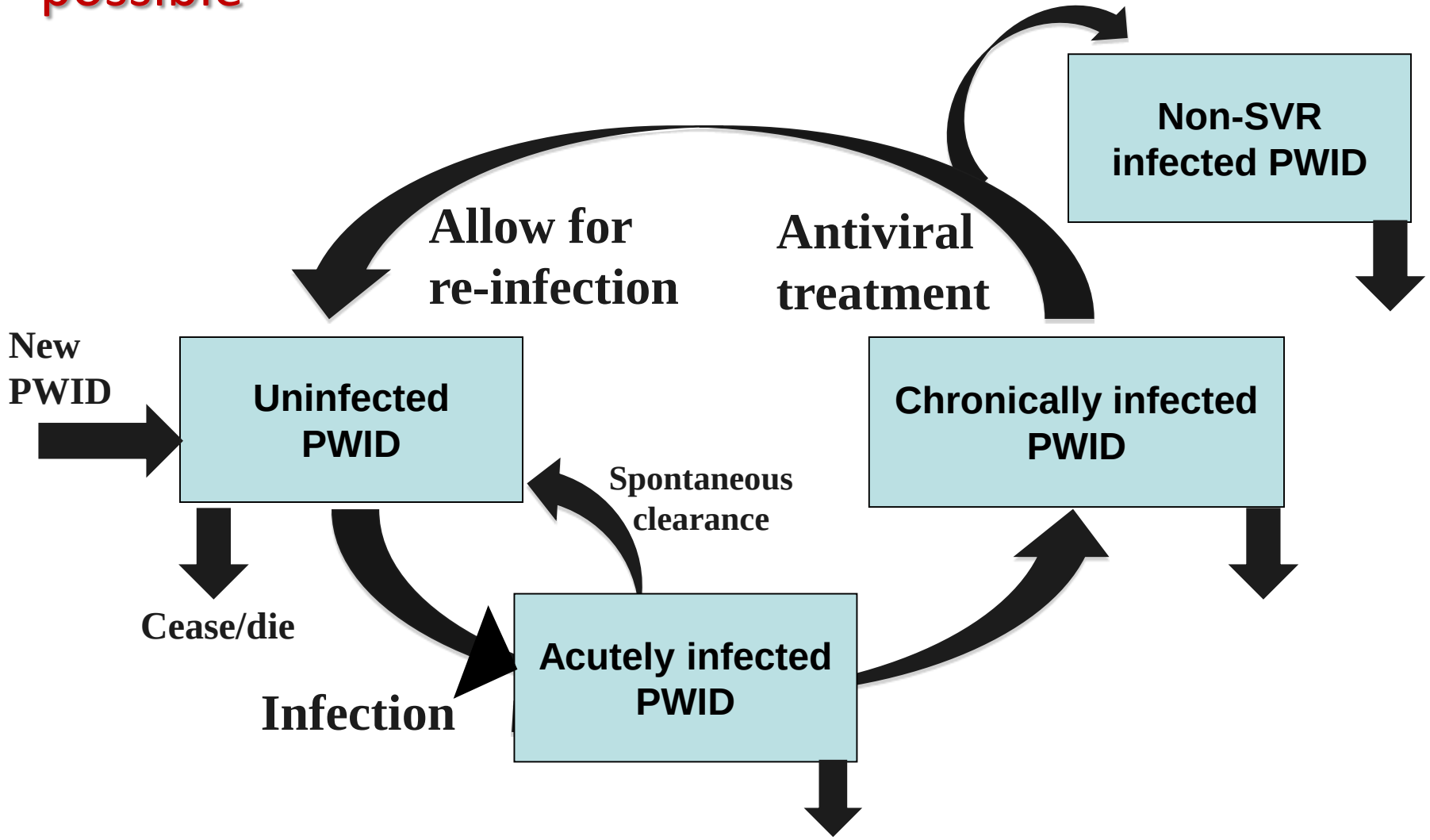
A model that suggested HCV elimination was possible



Martin et al. J Hepatology 2011; J Theoretical Biology 2011

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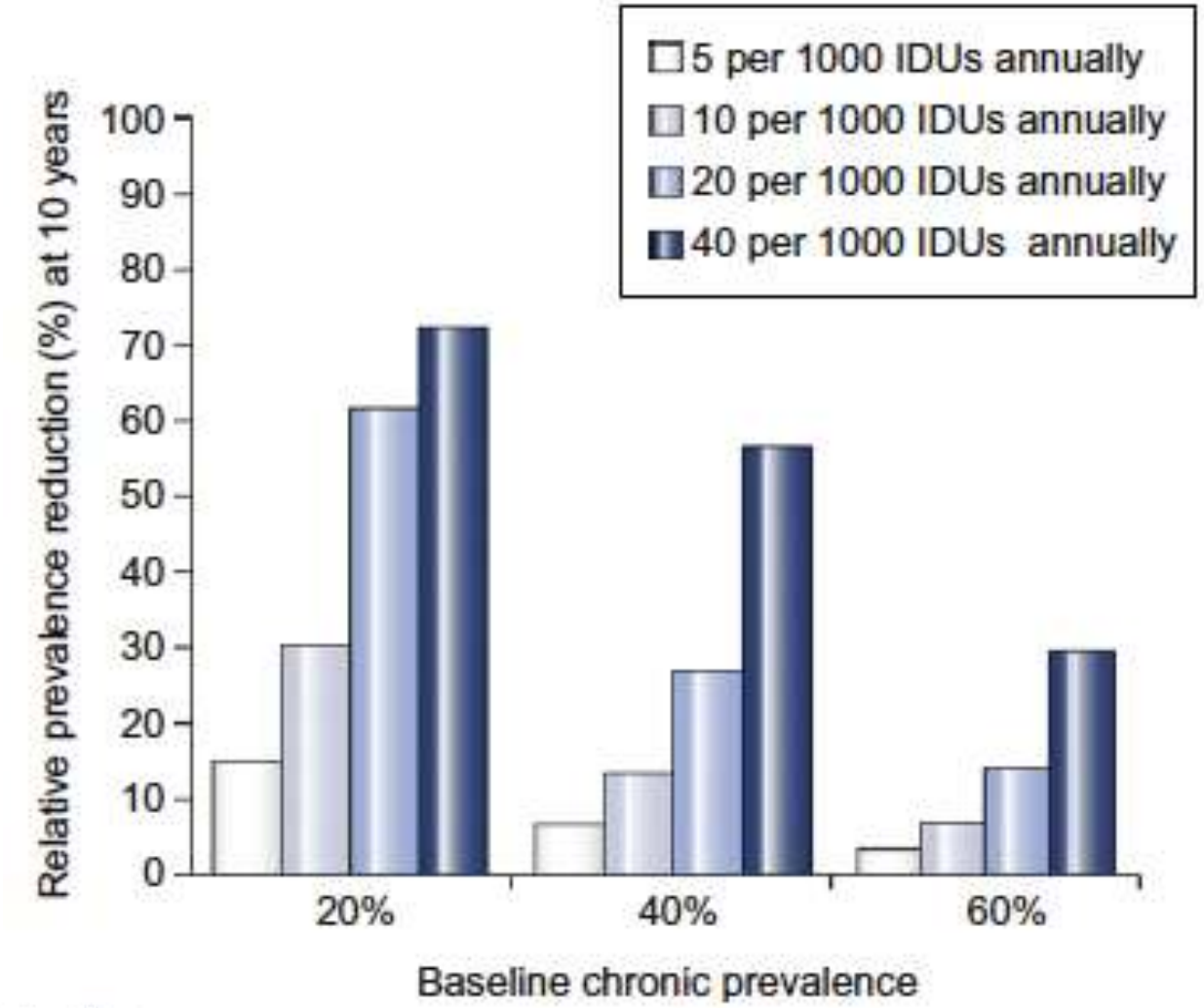
Prevention impact results: prevalence reductions at 10 years



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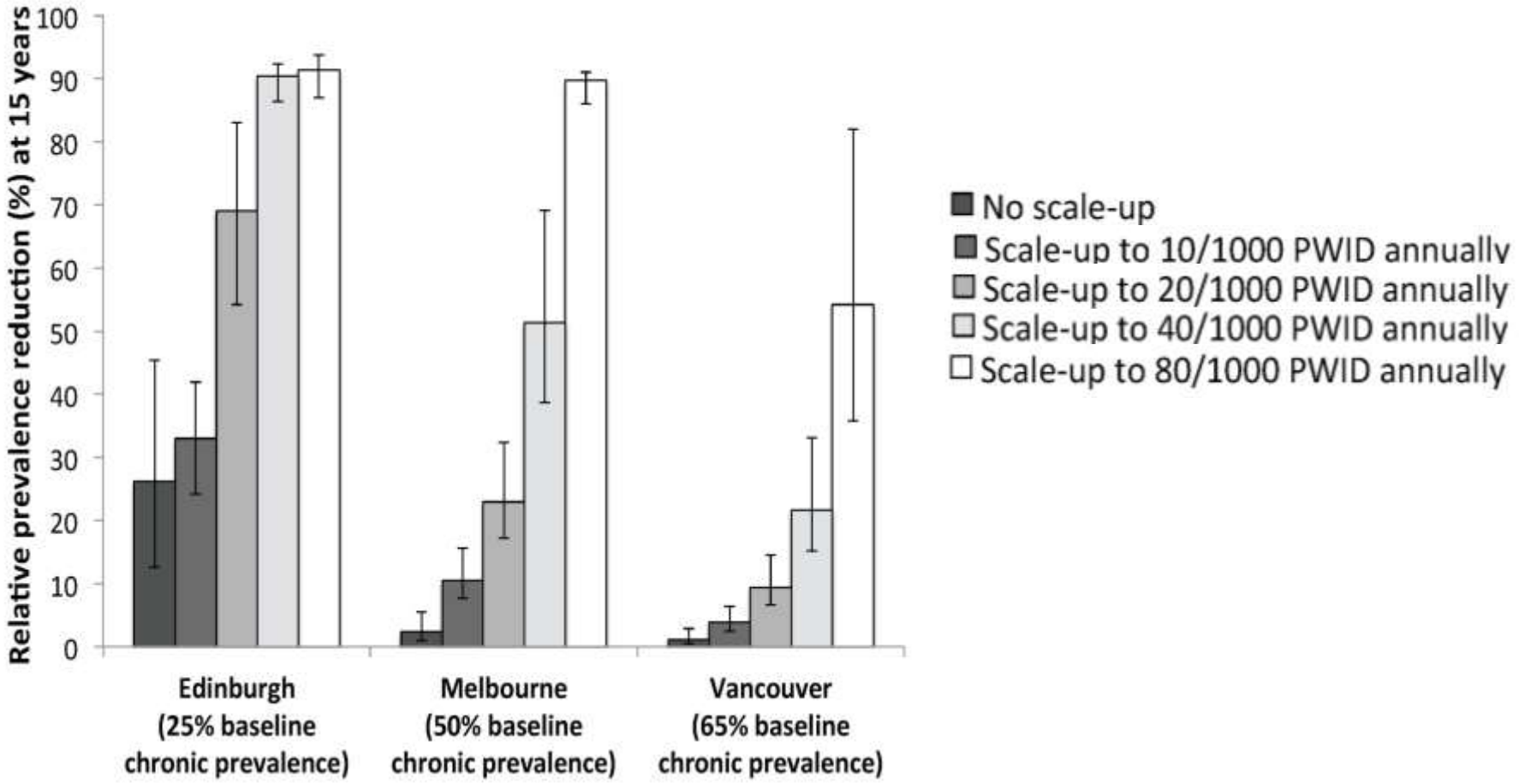
Martin et al. J Hep 2011

DYNAMIC MODELLING RESULTS:

HCV RELATIVE PREVALENCE REDUCTIONS AT 15 YEARS WITH DAAs



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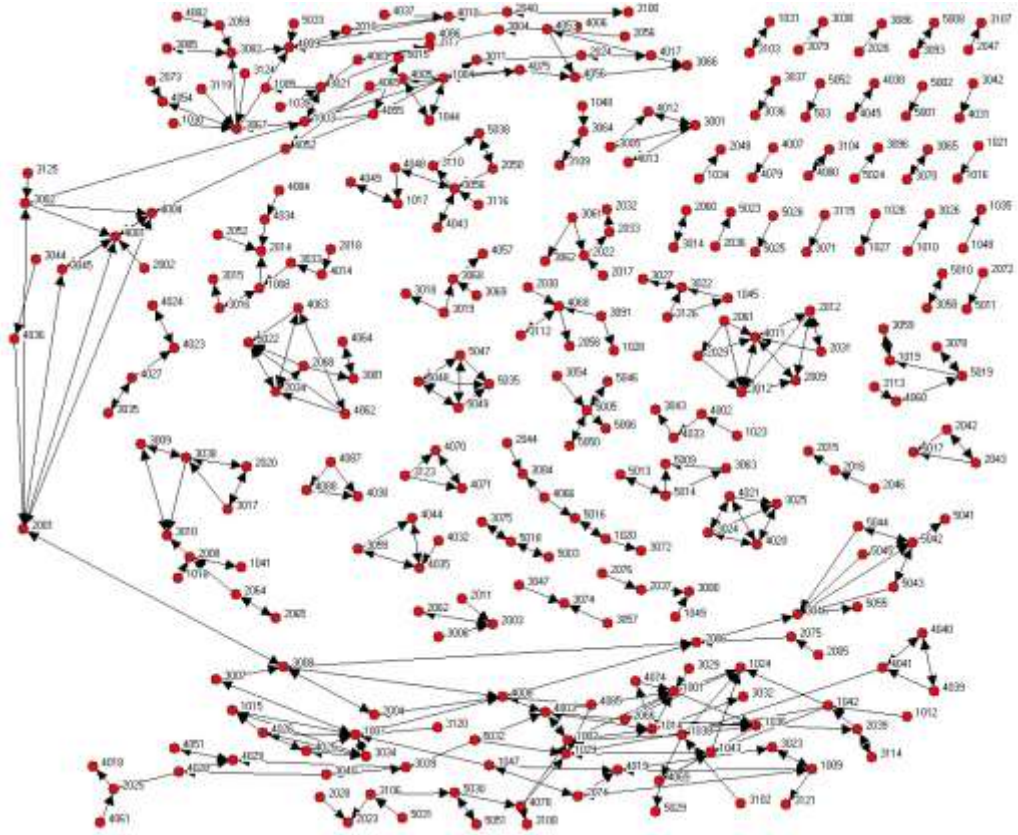
Martin NK, Vickerman P, Grebely J, Hellard M, Hutchinson SJ, Lima VD, Foster GR, Dillon J, Goldberg DJ, Dore G, and Hickman M. HCV treatment for prevention among people who inject drugs: modeling treatment scale-up in the age of direct acting antivirals. Hepatology 2013

The role of the injecting network on hepatitis C treatment and prevention.



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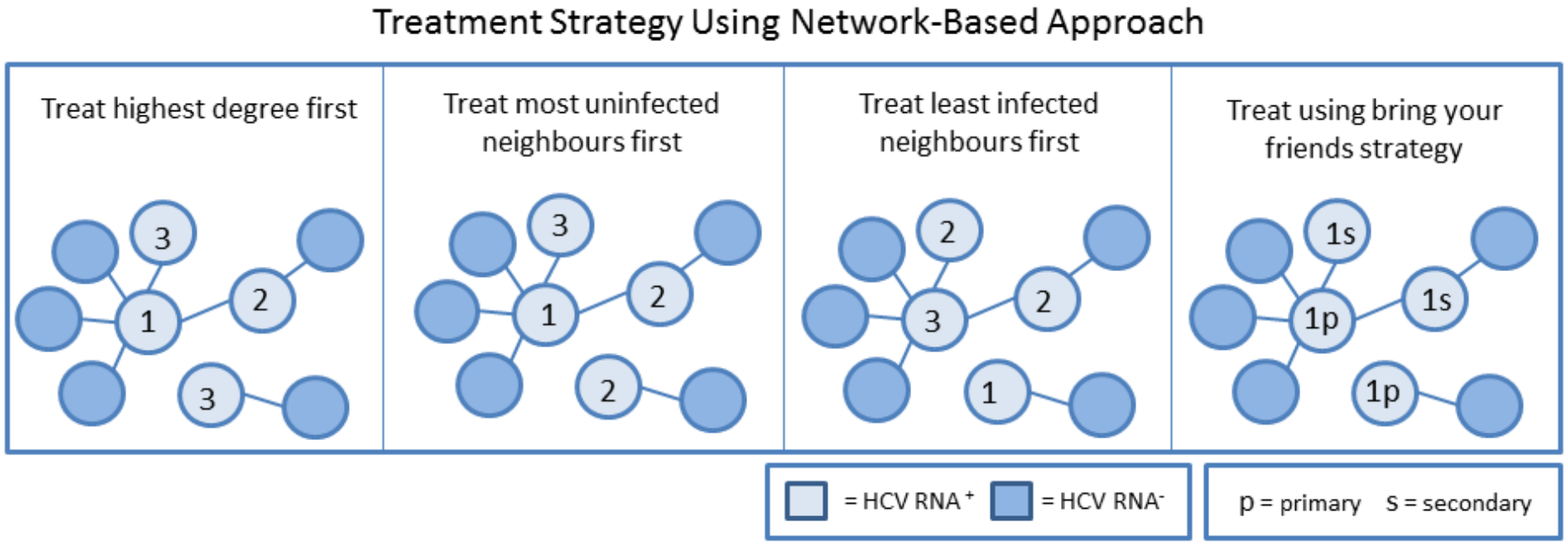
Different treatment strategies – including treat your friends strategy



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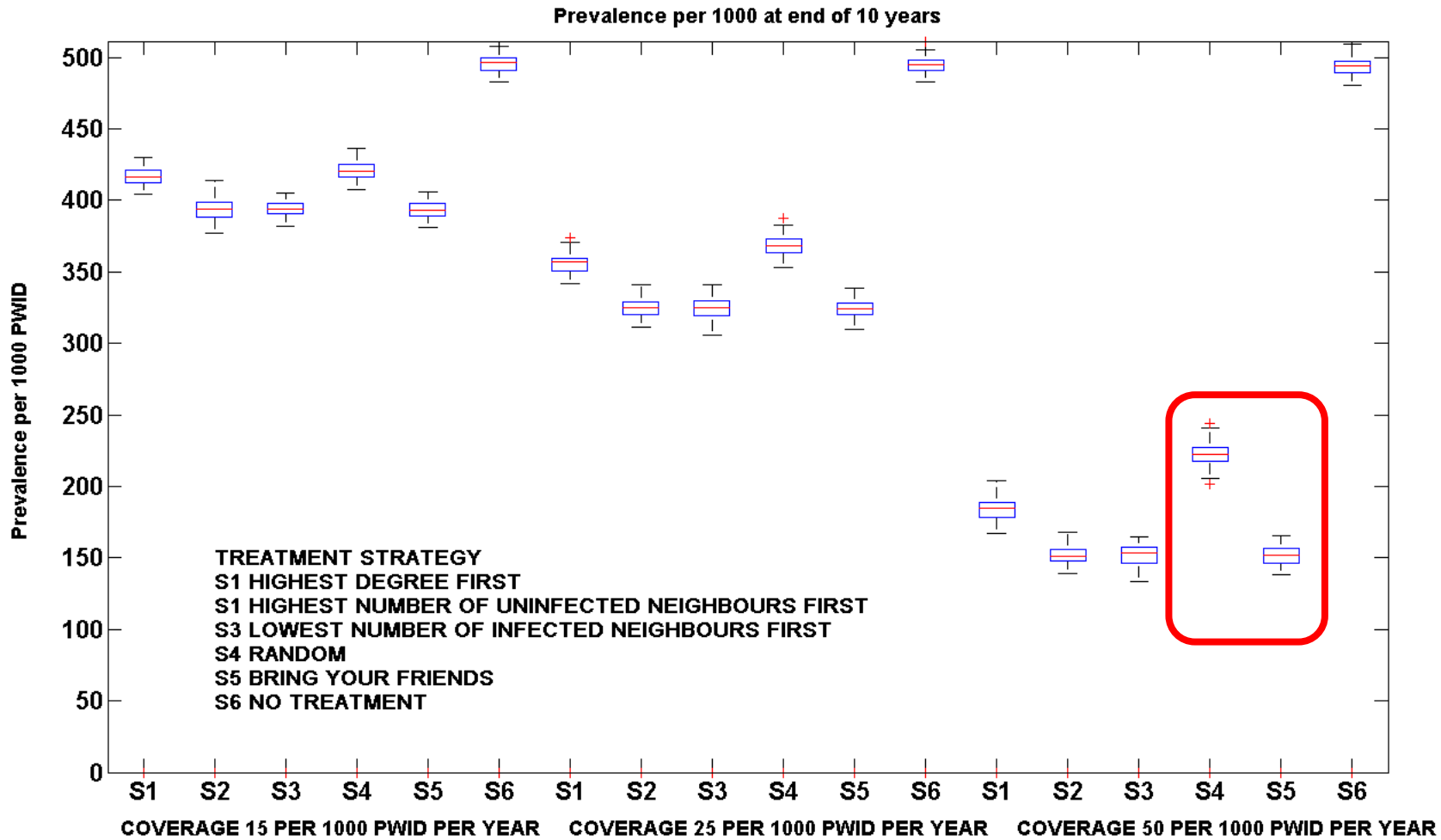
Treating injecting networks

Modelling the impact of treatment on prevalence at 10 years; 80% SVR



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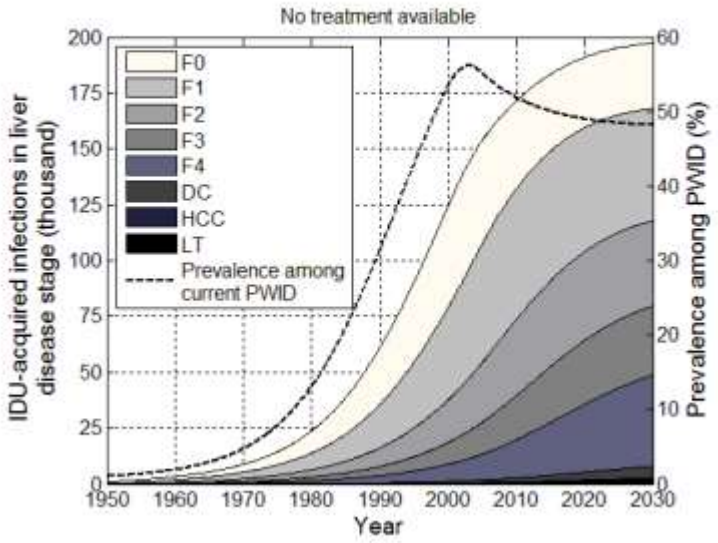
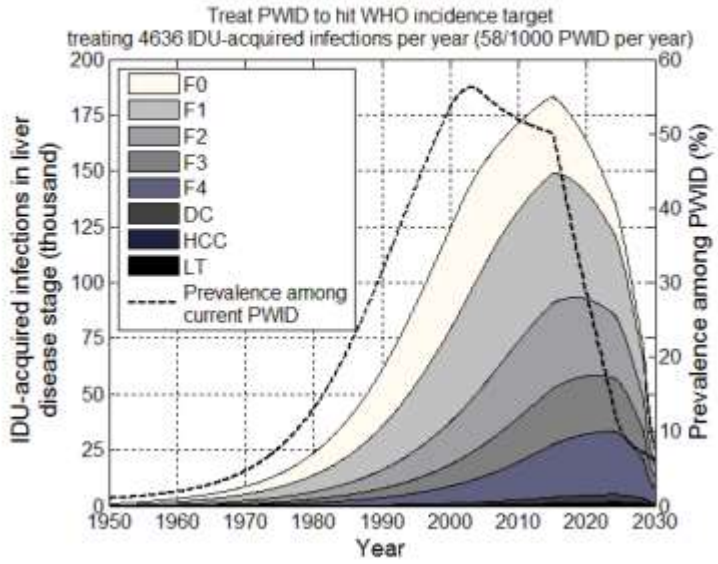
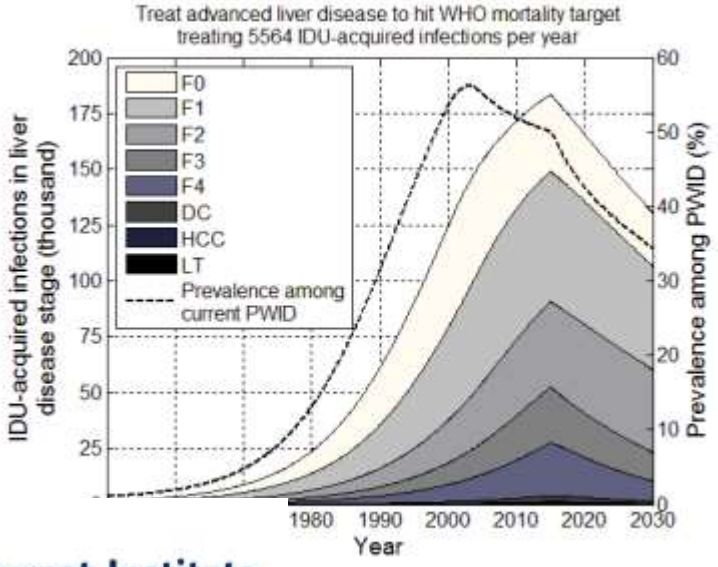
Hellard et al Hepatology 2014

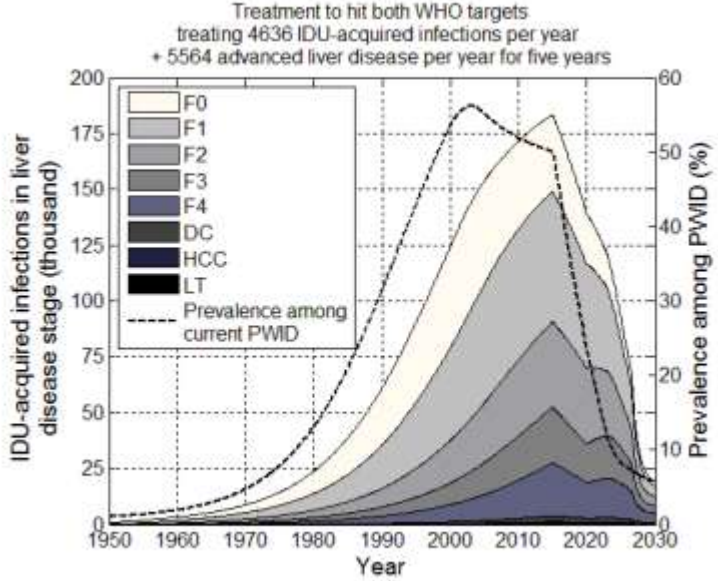
HCV related liver disease among current and former PWID in Australia

Projected outcomes 2015-2030 under different treatment scenarios









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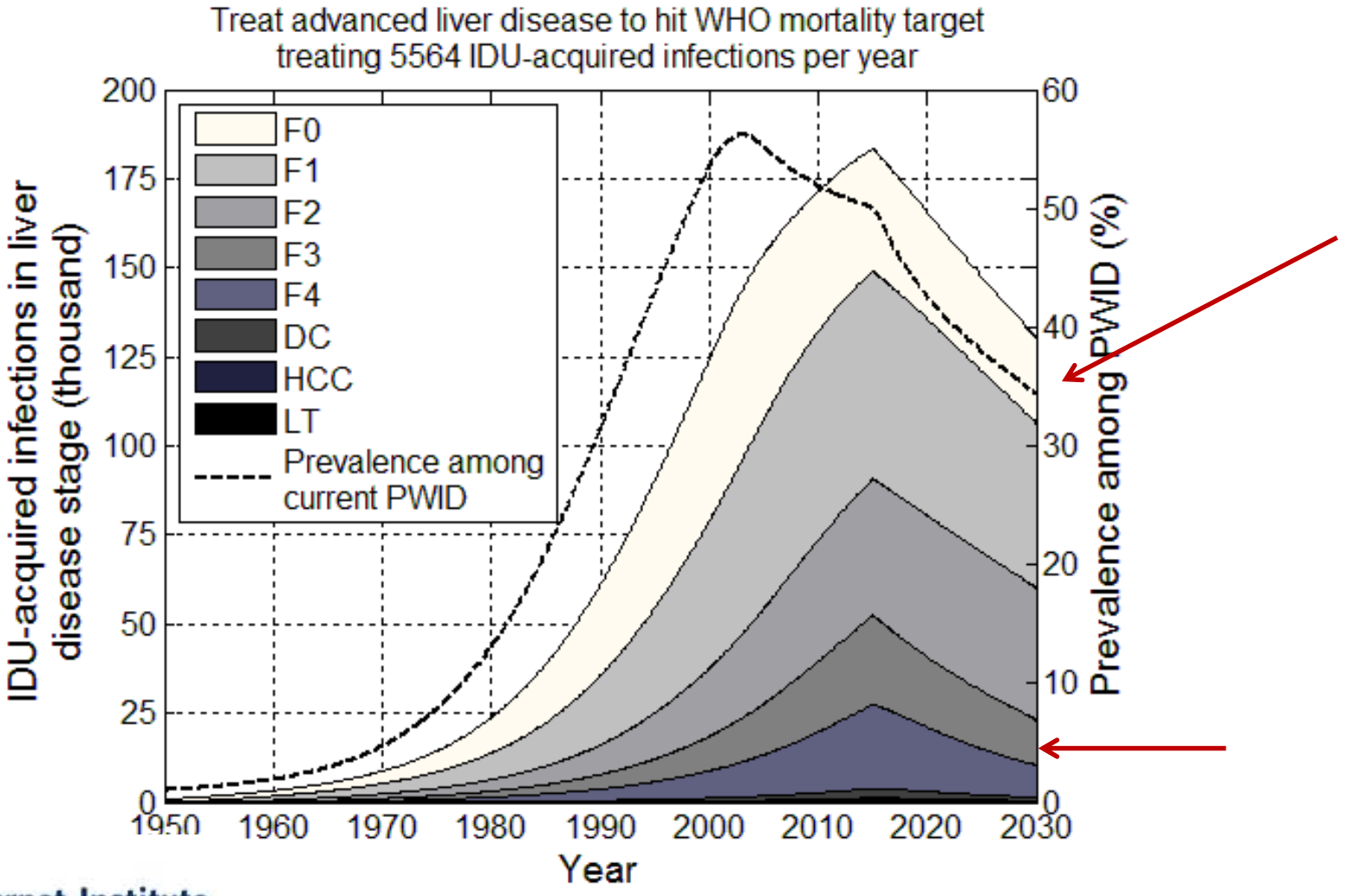
HCV prevalence remains at over 30% in 2030 if only treat advanced disease



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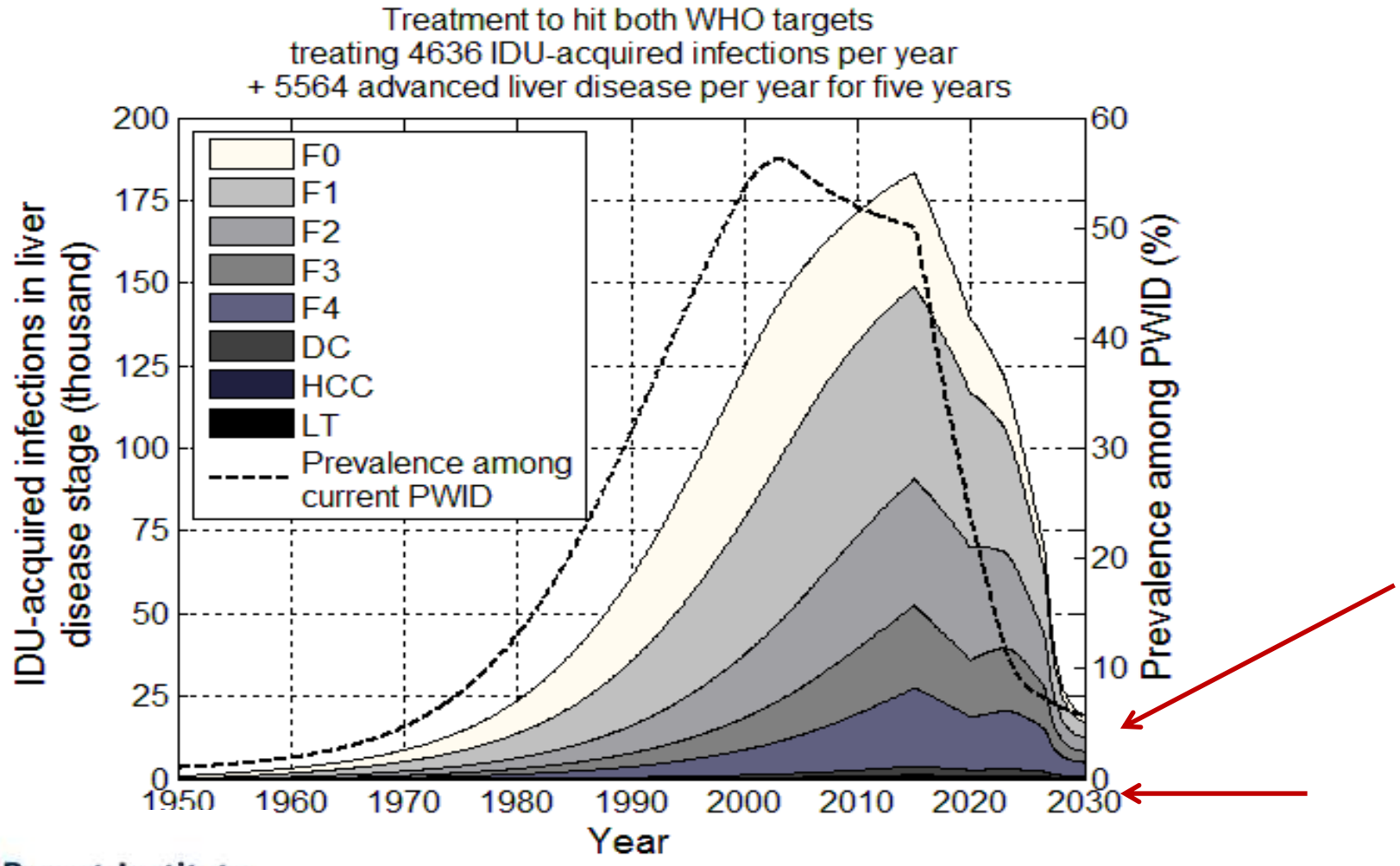
Treating PWID and advanced disease (for only five years) – stop deaths but also HCV prevalence < 10%



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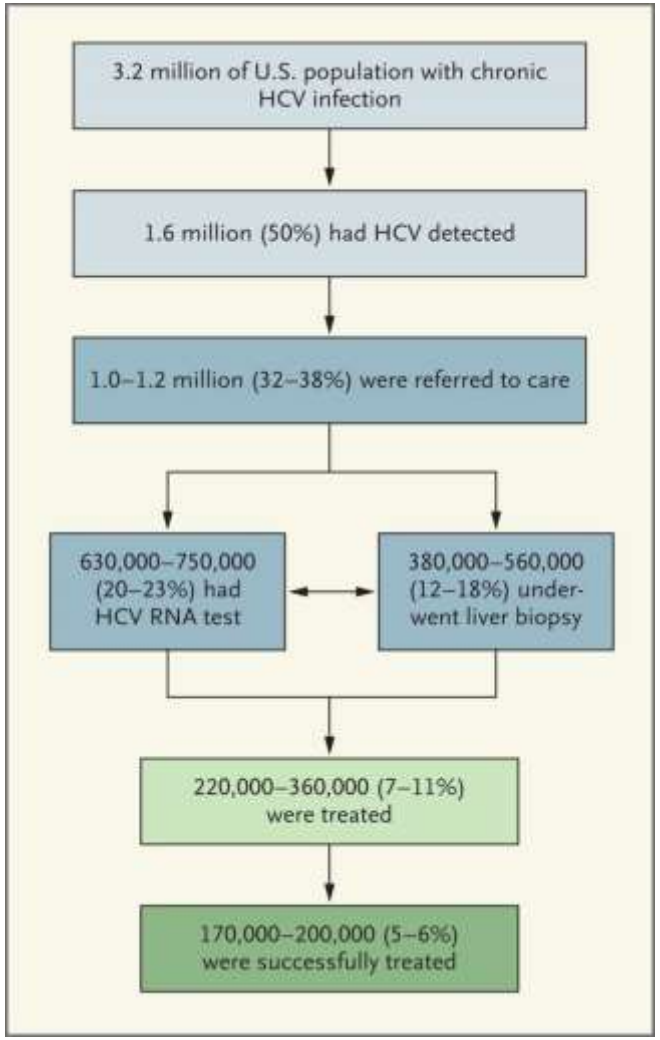
Not enough people are being treated overall



Let alone from marginalised populations

Holmberg NEJM 2013

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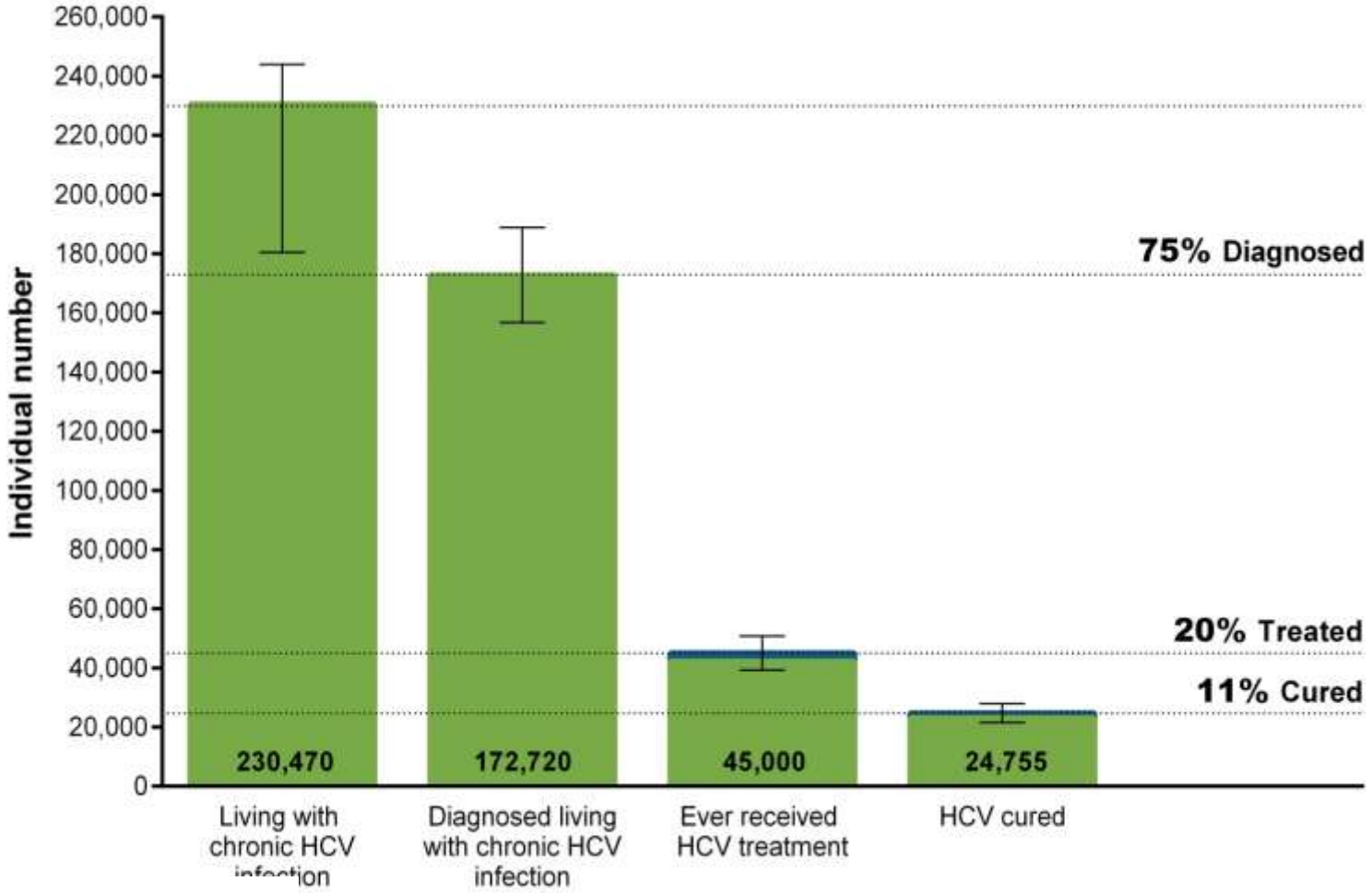
HCV treatment and care cascade in Australia



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Kirby Institute 2015

What do we need to address for Australia to achieve these targets by 2030 (but why not aim for 10 years)

- Everyone infected diagnosed
- Everyone diagnosed engaged in care
- Models of care that suit key affected populations
- Harm reduction
- Vaccine development
- Address stigma and discrimination
- Work force capacity

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HCV elimination in Australia

Predicated on a vital thing!

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You have to treat people who inject drugs !!!

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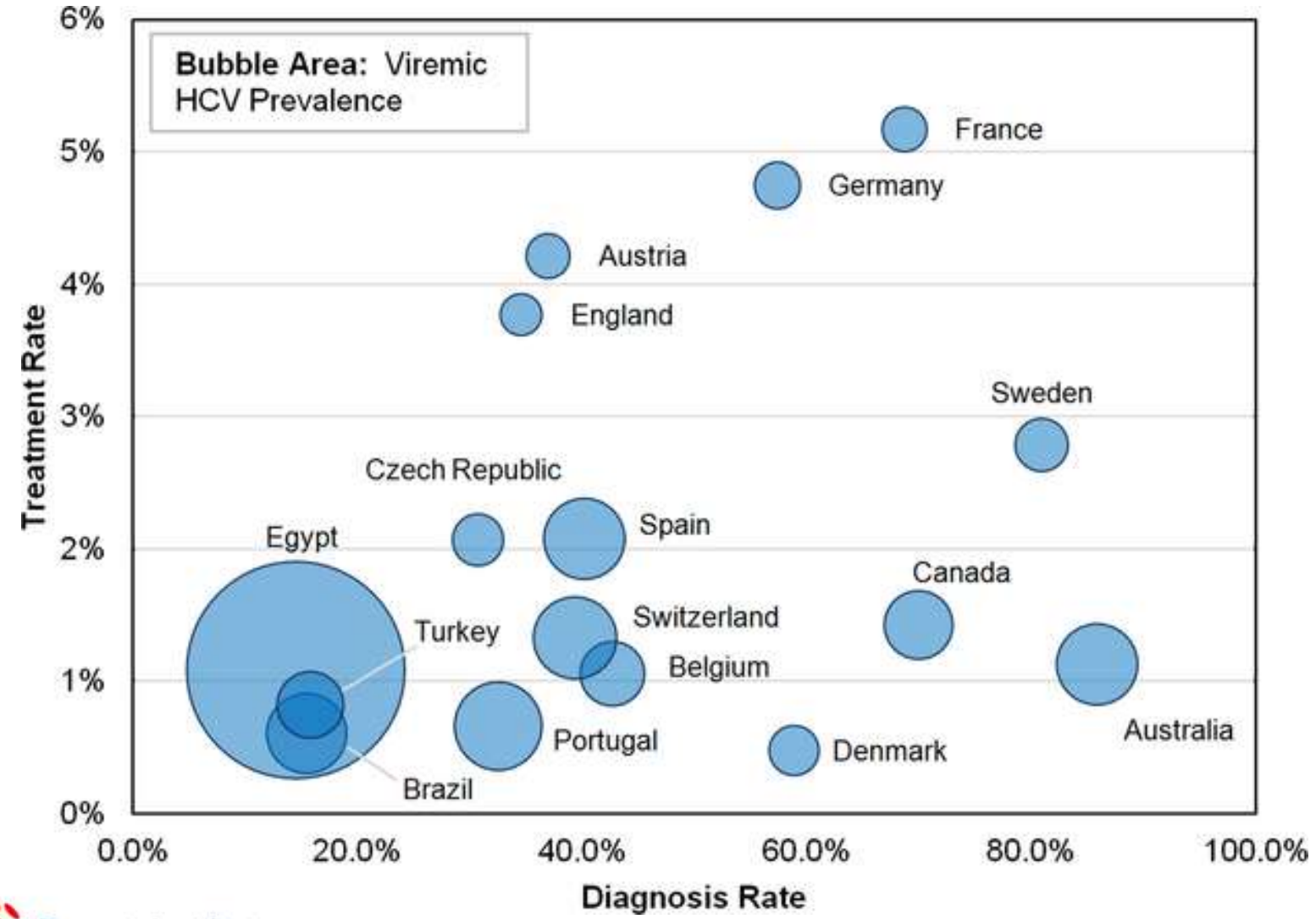
People who inject drugs

- PWID are at greatest risk of HCV infection in many developed and developing countries
- Drive transmission
- Many people in the correctional system have a history of injecting drug use
- Highly marginalised and stigmatised; activity is criminalised in most countries.
- To date, health services have been unsuccessful in channelling PWID into HCV treatment
- Many myths around HCV treatment outcomes in PWID

Hepatitis C diagnosis and treatment uptake



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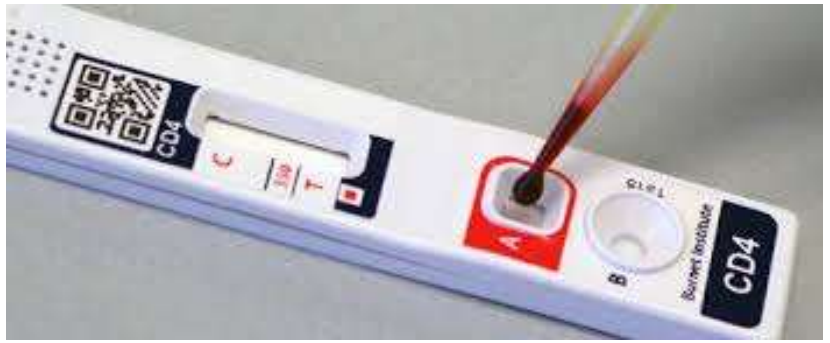
Dore GJ et al, *J Viral Hep* 2014

Increase testing – both screening and confirmation



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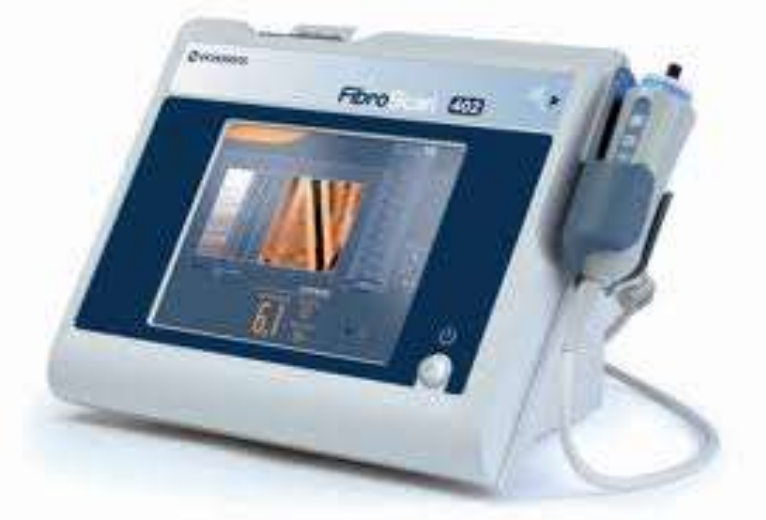
Measures of fibrosis

- Fibroscan
  - Transient elastography
  - Shear wave generated on skin, measure time taken to travel to a particular depth
  - Confounders
    - BMI
    - High ALT (inflammation)



Key will be ensuring this isn't a bottle neck

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There is no one “best” model of care

The Prime Study

TAP STUDY

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But before I get into the models of care – to dispel a few myths

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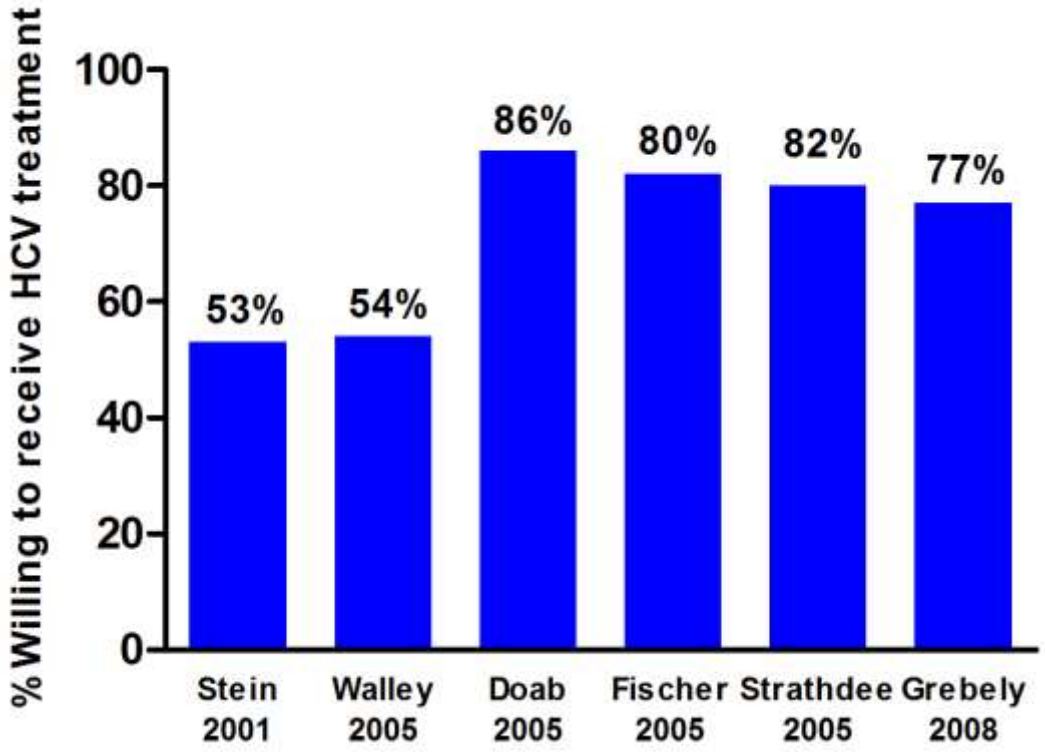
"Myth" that PWID don't want treatment – but even in the "interferon era"- many PWID reported they were interested in treatment



Stein MD, et al. Drug and Alcohol Dependence 2001. Walley AY, et al. J Substance Abuse Treatment 2005. Doab A, et al. Clinical Infectious Diseases 2005. Fischer B, et al. Presse Med 2005. Strathdee S, et al Clinical Infectious Diseases 2005. Grebely J, et al. Drug and Alcohol Dependence 2008.

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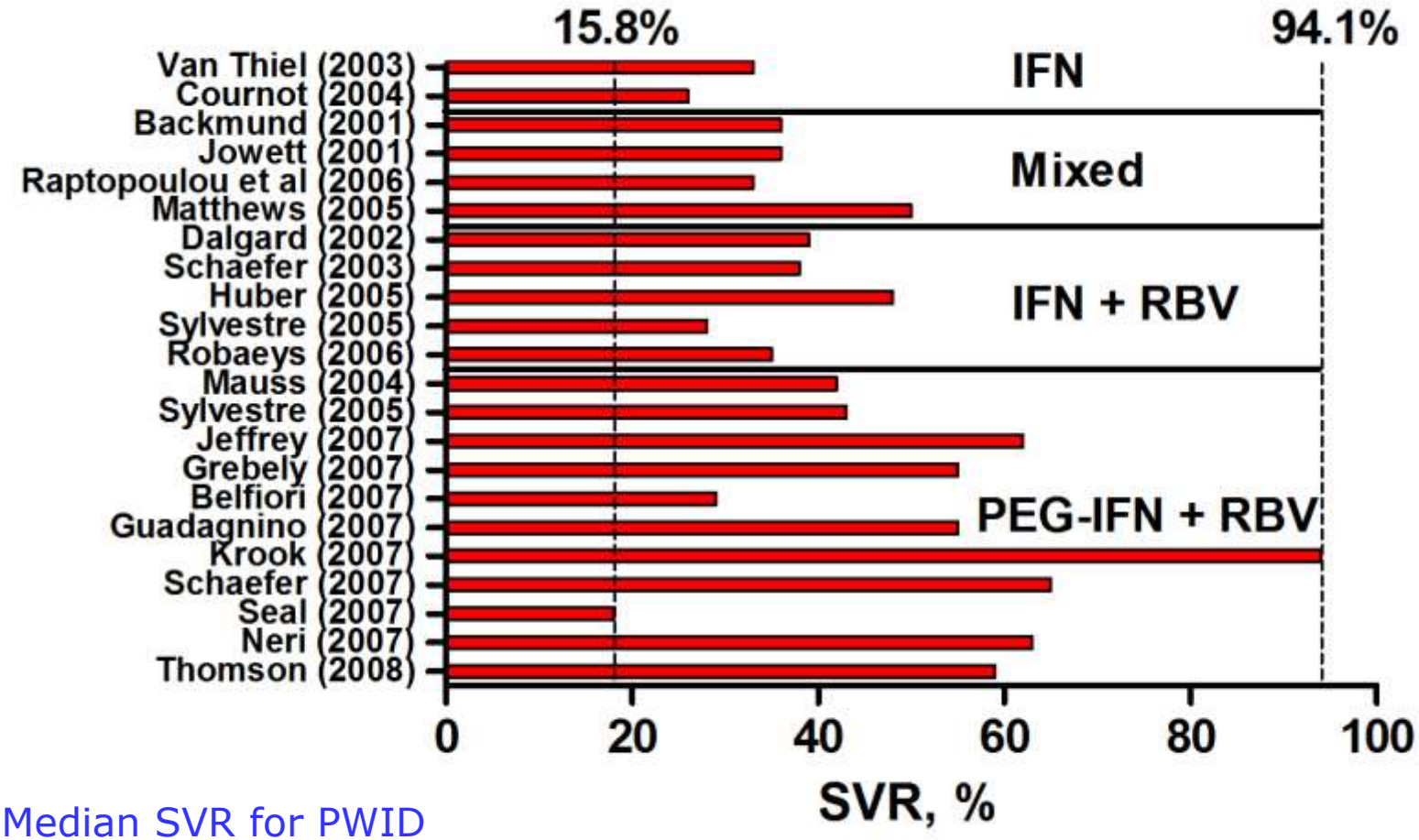
Treatment outcomes for PWID with HCV



Median SVR for PWID

- Regardless of treatment regimen - 40.6%
- Peg interferon/ribavirin - 54.3% (range, 18.1%–94.1%), compared with 54%–63% for the comparable large treatment trials for HCV

Hellard M, et al. Clinical Infectious Diseases 2009.

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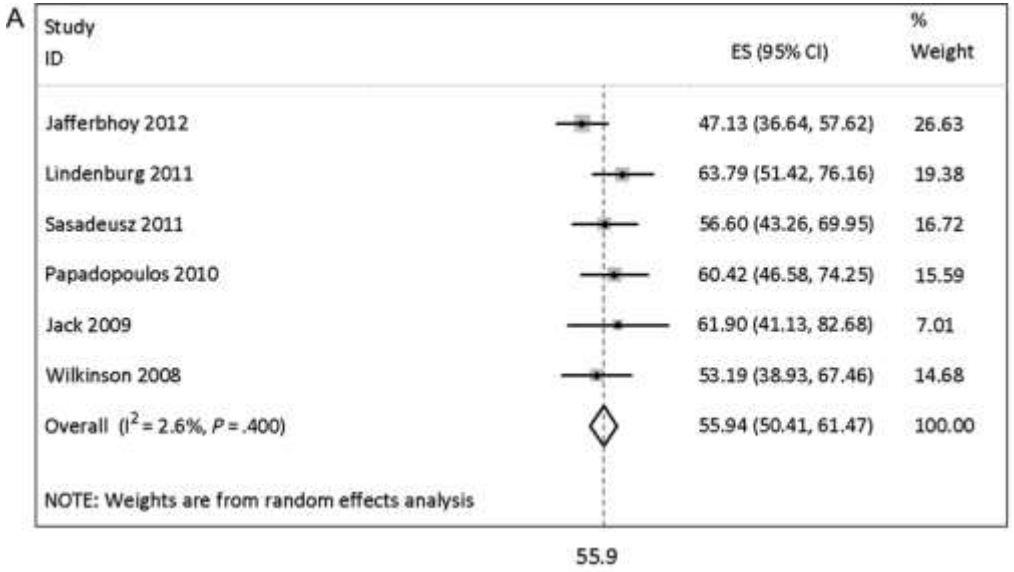
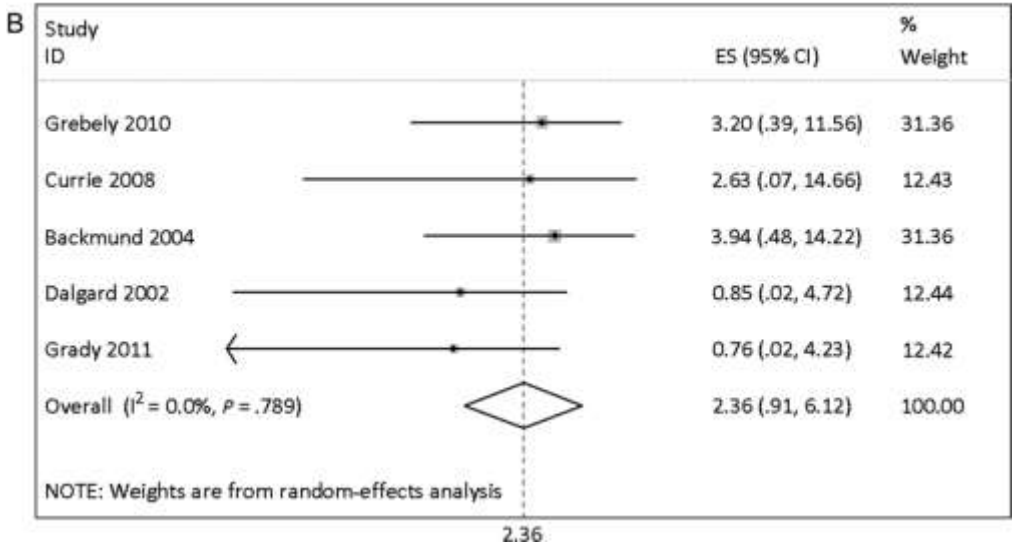
Systematic review of HCV treatment outcomes in people who use drugs





A. - Forrest plot of studies examining treatment sustained virologic response among people who use drugs (PWUD) with chronic hepatitis C virus

B, Forrest plot of studies examining reinfection among ever-PWUD treated for chronic HCV.

Aspinal et al CID 2013

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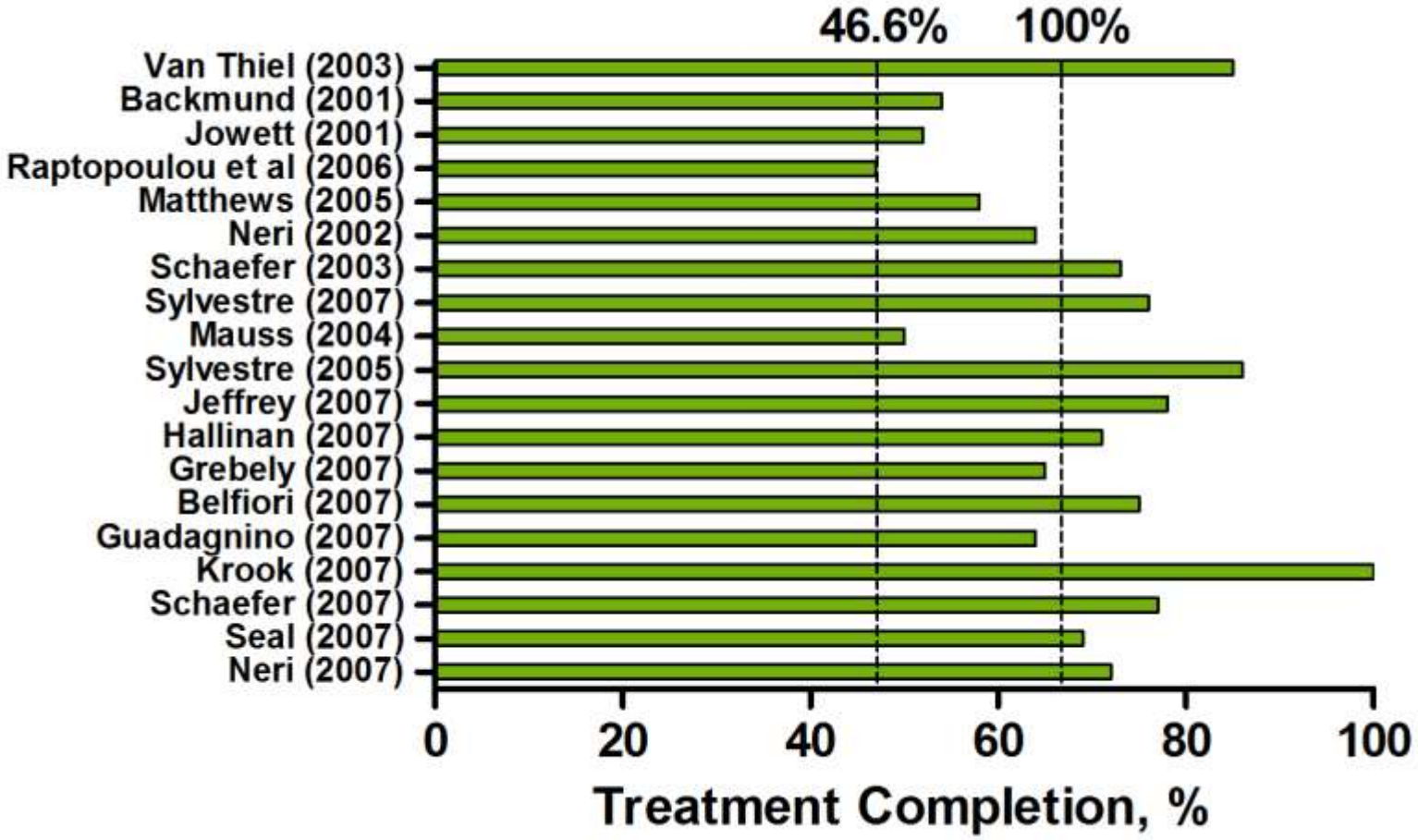
Treatment completion



- Median completion overall: 70.7%
- Only 1 of 5 evaluable studies demonstrated a difference in treatment completion rates in IDUs vs. non-IDUs

Hellard M, et al. Clinical Infectious Diseases 2009.

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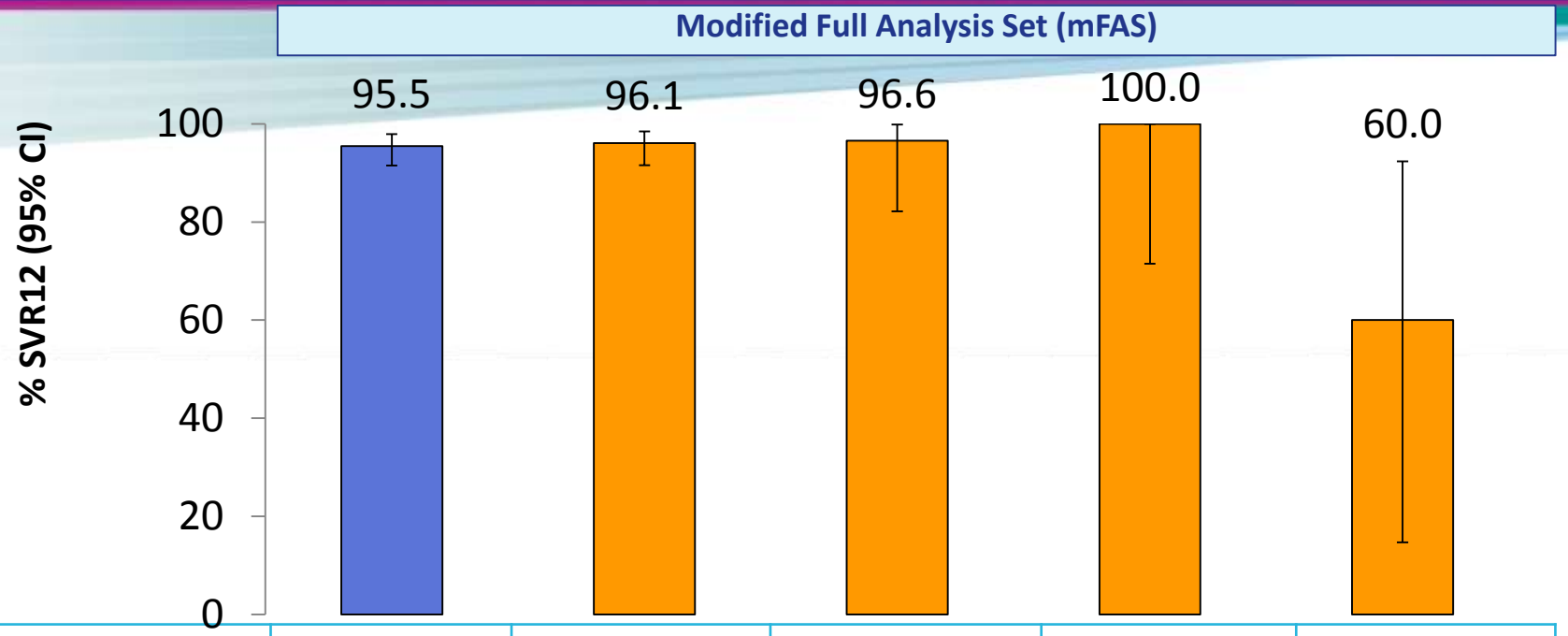
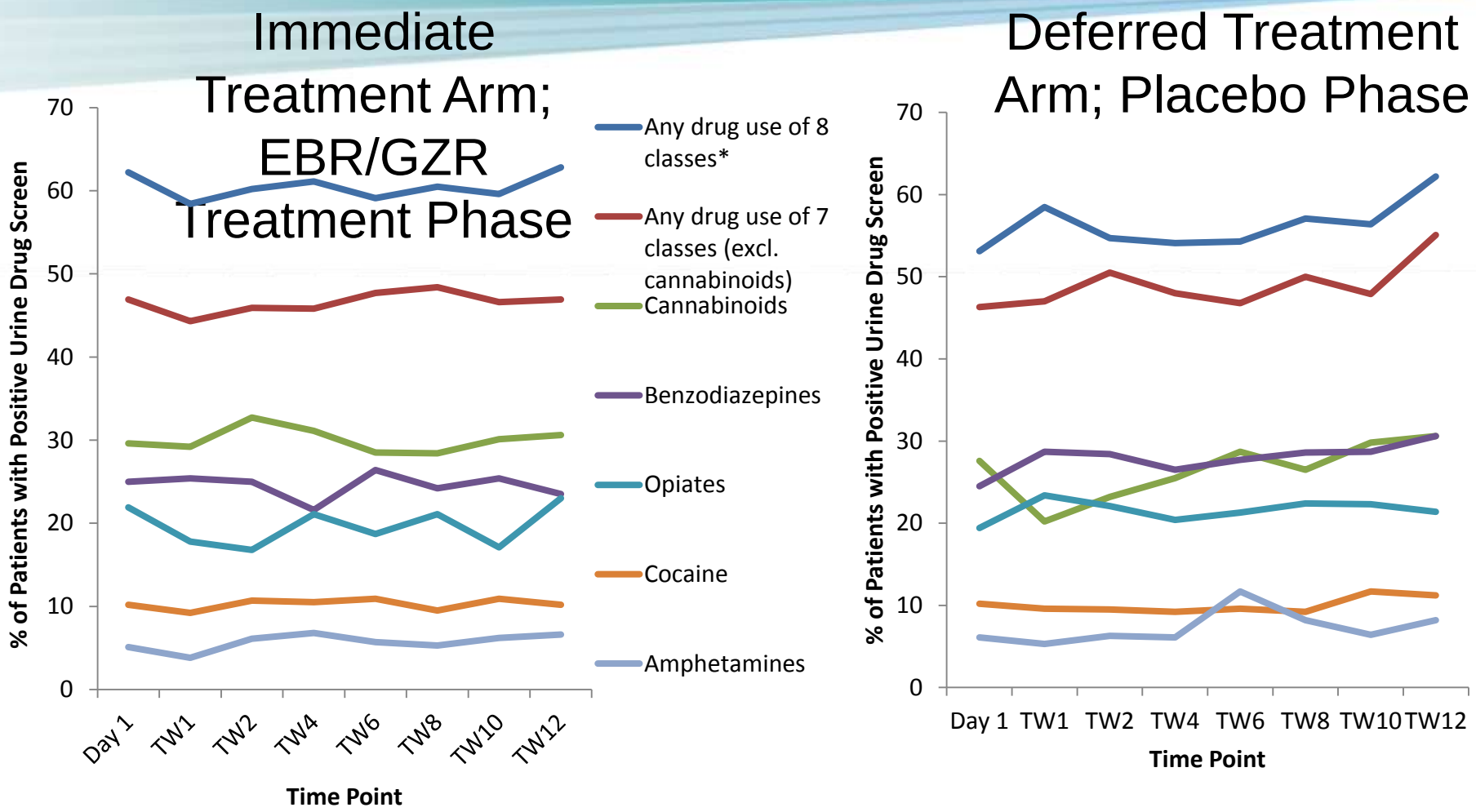
SVR12 IN THE IMMEDIATE TREATMENT GROUP: MODIFIED FULL ANALYSIS SET (mFAS)



	All GT†	GT1a*	GT1b	GT4	GT6
	189/198	147/153	28/29	11/11	3/5
Failures					
Relapse	7	4	1	0	2
Discontinuation	2	2	0	0	0
Reinfection – counted as success					
	5	3	0	0	2
LTFU or discontinued unrelated to Virologic Failure – excluded from mFAS analysis					
	3	1	1	1	0

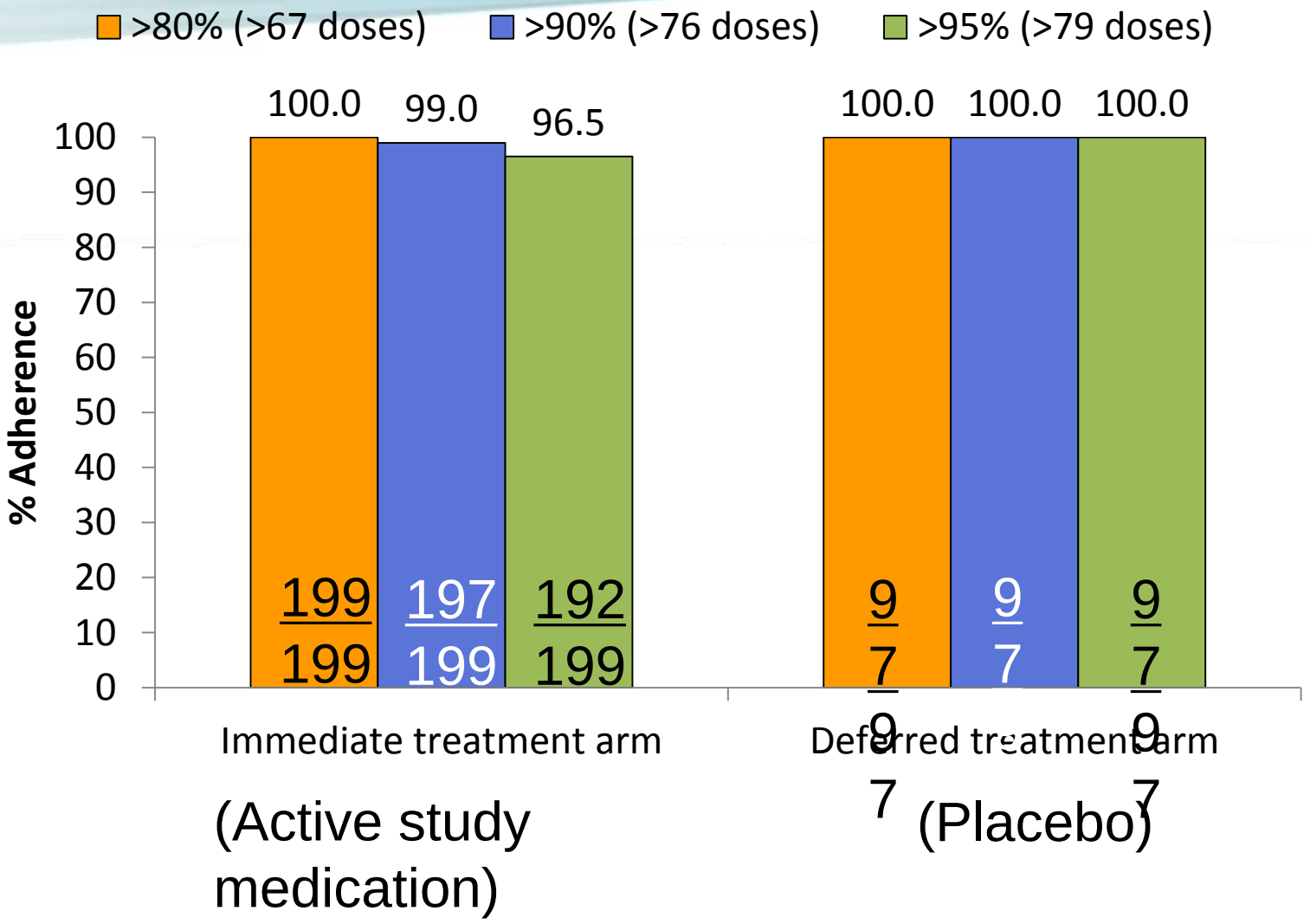
*Includes one subject with mixed infection (GT1a and GT1b) who achieved SVR12

URINE DRUG SCREEN RESULTS: DAY 1 TO TREATMENT WEEK 12



* 8 drug classes: amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, opiates, phencyclidine, propoxyphene

ADHERENCE


>80% (>67 doses)
>90% (>76 doses)
>95% (>79 doses)
% Adherence
100
90
80
70
60
50
40
30
20
10
0
100.0
99.0
96.5
100.0
100.0
100.0
199/199
197/199
192/199
97/97
97/97
97/97
Immediate treatment arm
Deferred treatment arm
(Active study medication)
(Placebo)

Myth – people who drink alcohol cannot be successfully treated for hepatitis C

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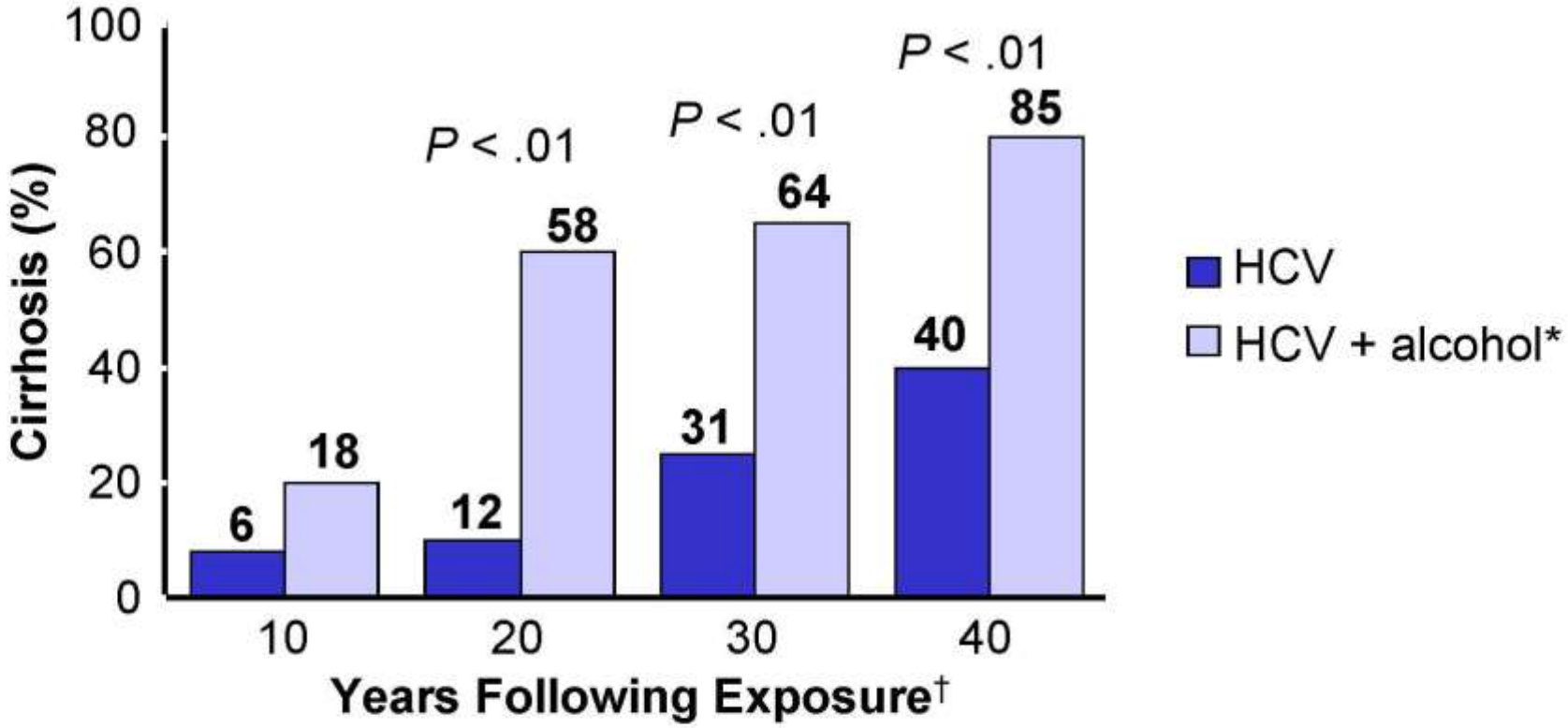
Alcohol Consumption Increases Risk of Cirrhosis in HCV Patients



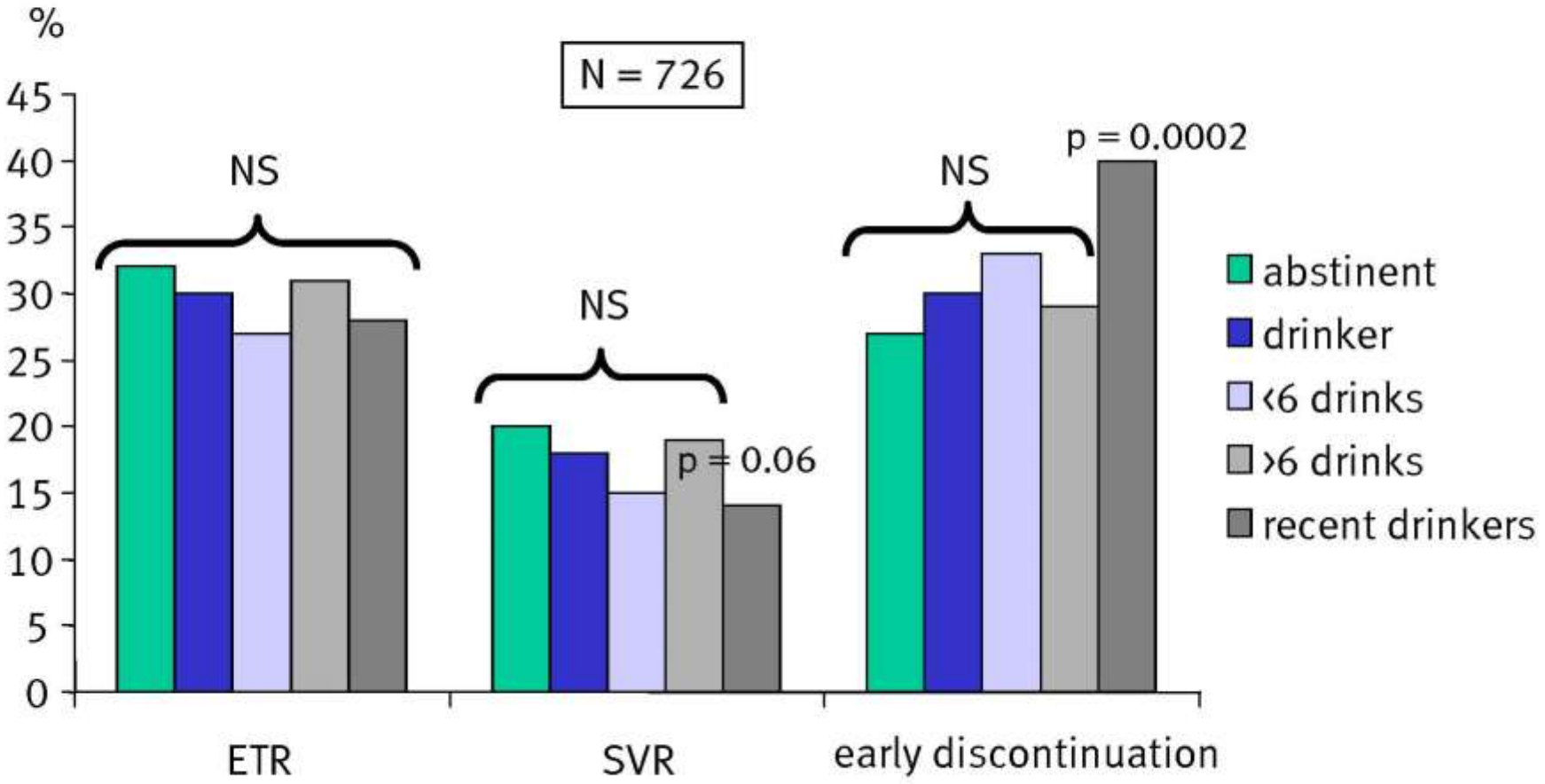
*Excessive alcohol intake characterized as > 40 g/day for women and > 60 g/day for men.
†Duration of exposure defined as either first blood transfusion before 1990 or from the year of initial intravenous drug use.

Wiley TE, et al. Hepatology. 1998:28:805-809.

Acknowledgment – Philip Bruggmann

Multicentre trial on alcohol use and HCV treatment

ETR, SVR und discontinuation in alcoholics



Anand et al., Gastroenterology 2006;130:1607-16

Acknowledgment – Philip Bruggmann

Illicit drug use during treatment

- No evidence that occasional injecting during treatment has an effect on chances of treatment success
- Regular injecting drug use (daily or every second day):
  - One study found that this made people less likely to complete the regimen
  - No difference has been observed in SVR rates
  - Numbers are small
- In a recent study active users were less likely to attain SVR than former users. However 'active' was not defined
- Low observed reinfection rates after treatment (0-2.5/100 person-years cf 31-47/100 person-years after spontaneous clearance)

Key sources: Hellard, Sacks-Davis, Gold 2009; Alvarez-Uria, Day et al 2008

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Hepatitis C models of care

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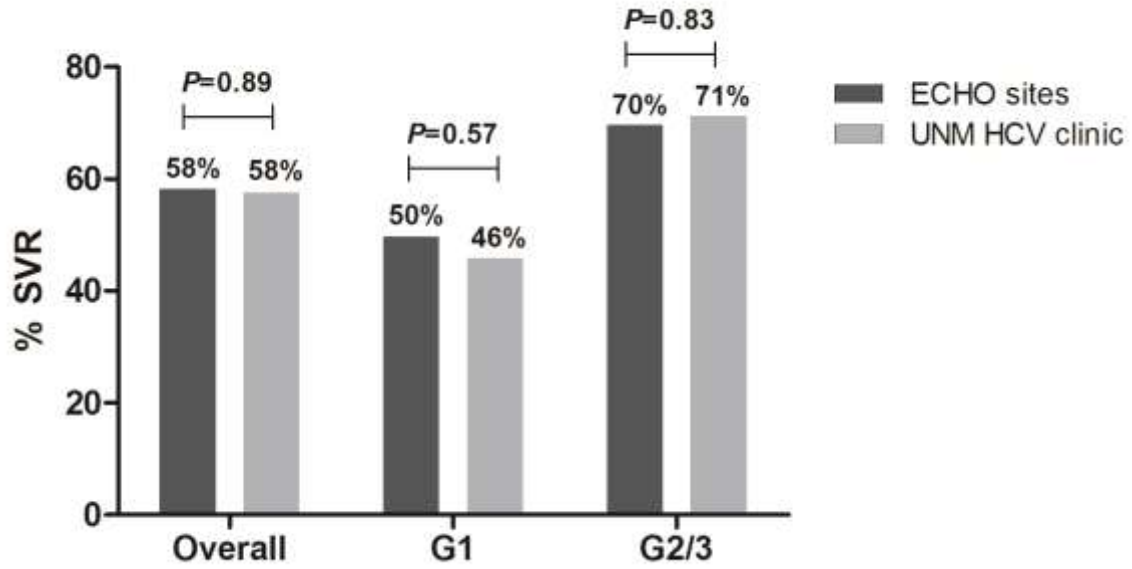
Project ECHO

Extension for Community Healthcare Outcomes (ECHO) model

- Integration of community-based health centres using telehealth
- Training and support for primary care providers
- Initially 21sites in rural areas and prisons
- SVR compared at the ECHO sites (n=261) and UNM HCV clinic (n=146)



Concept now move beyond New Mexico to many other locations

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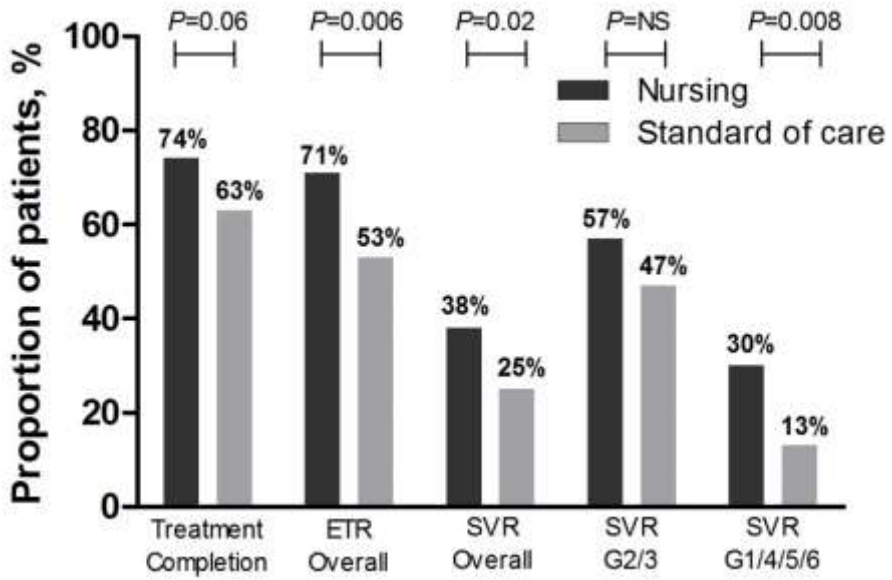
Arora *N Engl J Med* 2011; 64:2199-2207

Randomised trial measuring the impact of nurse education conducted in France

- Therapeutic education by a specialised nurse increased the response of patients with hepatitis C to therapy, particularly in difficult-to-treat patients



Larrey D, et al. Clin Gastro Hepatol 2011

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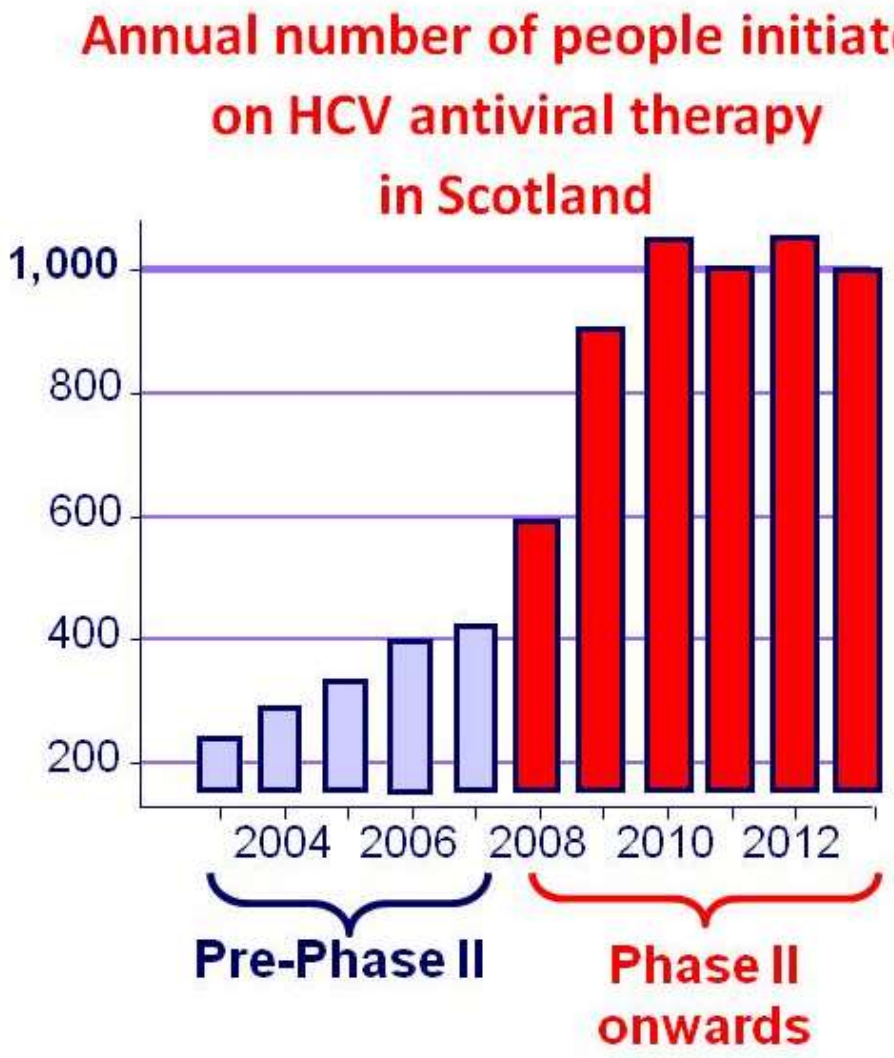
Scottish Hepatitis C Action Plan



- 7-fold rise in the number of prisoners initiated on therapy:
  12% of those initiated during 2009-13,
- Great majority of those treated are now PWID:
  81% of those initiated during 2012-13,

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Current models of care in Australia

- Standard
  - GP refer to specialist in tertiary hospital outpatient clinics
  - Shared care in consultation
  - Increasing access to treatment in prison

- Nurse led models of care

- Since 2011 in Victoria 10 community hepatitis nurses funded
  - Nurse led service was developed to link large tertiary centres to primary health care services (PHCS)
  - Structure variable according to local environment
    - Worked in PHCS
    - Triage
    - Clinical assessment
    - Blood tests +/- fibroscan
    - Facilitated appointments with clinician for assessment and managed patient throughout treatment

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Victoria - successful community based treatment of hepatitis C in PWID

- The community hepatitis service aimed to increase access to HCV care, targeting PWID
- This study describes the cascade of care for patients referred to the community hepatitis nurse at three outreach PHCS affiliated with The Alfred Hospital
  - Access Health, St Kilda
  - Innerspace, Collingwood
  - Frankston Health
- A retrospective audit of all patients referred to the Alfred community hepatitis service from April 2011 until August 2014

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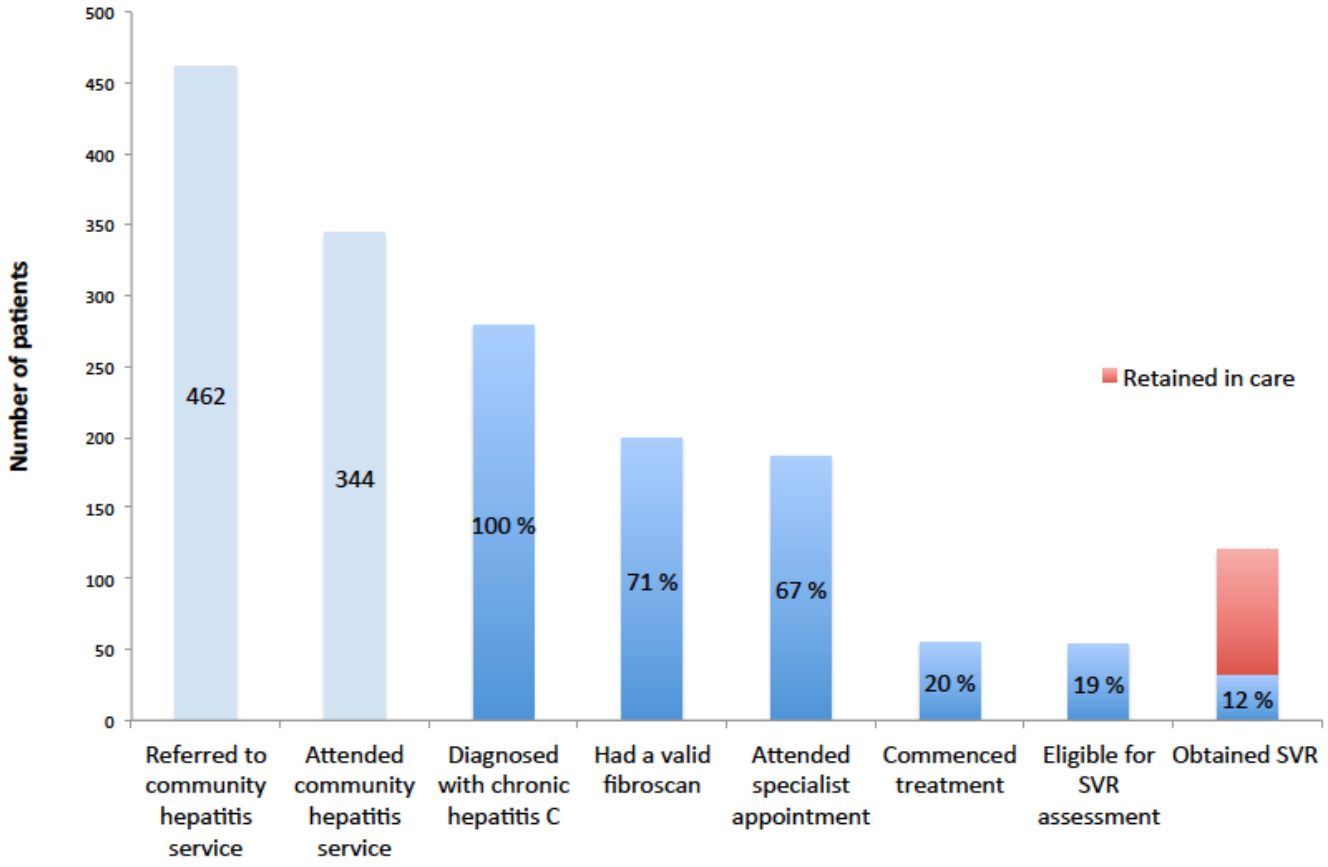
Cascade of care for Alfred community hepatitis nurse



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Wade AJ et a lPlos One 2015

TheAlfred

Other current Australian pilot models of care

- Successful treatment of patients with hepatitis C in rural and remote Western Australia via telehealth
  - 50/53 referred patients started treatment
  - SVR 72%

Nazareth S, J Telemed Telecare 2013

- Effectiveness of a nurse-led outreach program for assessment and treatment of chronic hepatitis C in the custodial setting
  - Nurse triaged specialist involvement
  - Treatment commenced in 28%
  - SVR ITT 44%

Lloyd A, CID, 2013

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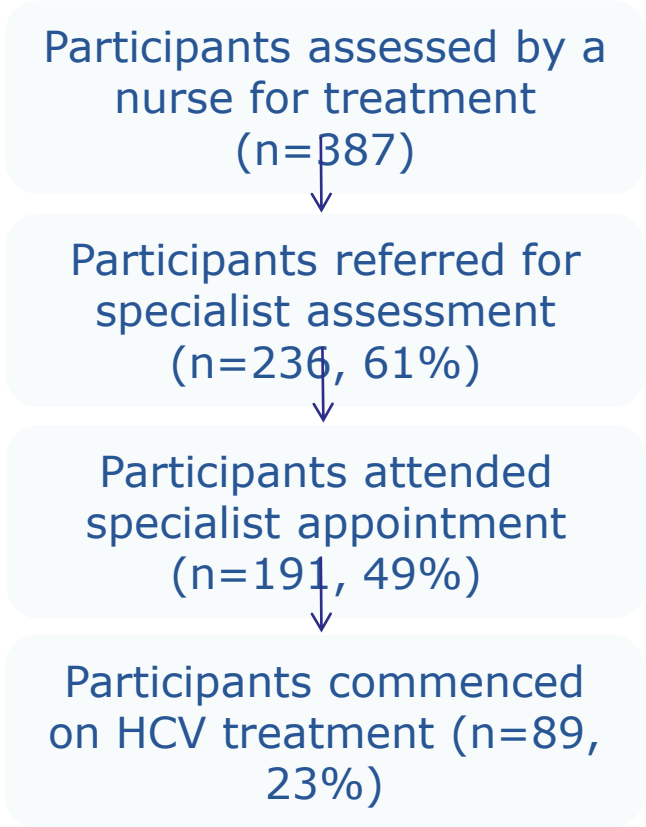
Enhanced HCV assessment/treatment in the drug & alcohol setting - NSW

- Enhanced Treatment of HCV in the OST Setting (ETHOS)
- Evaluation of HCV assessment and treatment at a network of 9 clinics - 6 OST clinics and three community



Alavi M, et al. *Clinical Infectious Diseases* 2013

Summary

- This community hepatitis service successfully provided HCV care and treatment to a significant number of PWID.
- The SVR rate is comparable to patients treated in tertiary institutions.
- Whilst challenges remain, this study highlights the potential for community provision of HCV therapy, including directly acting antivirals, to PWID a group with a high prevalence of HCV infection.

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Current research

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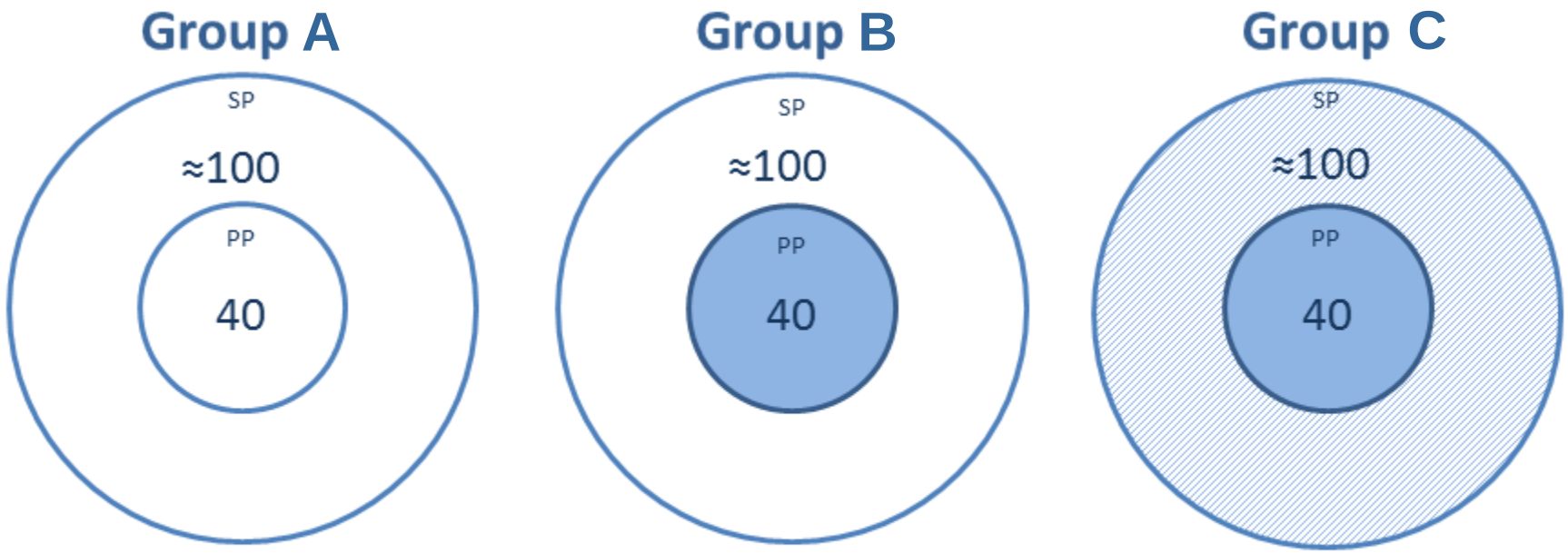
The TAP Study
(Treatment and Prevention)

A community based study measuring the impact of hepatitis C treatment on disease transmission using a networks based approach.



PP = Primary participants (100% HCV RNA$^+$)
SP = Secondary participants (estimated 50% HCV RNA$^+$, 50% HCV RNA$^-$)

= Treatment
= HCV RNA$^+$ treatment only

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TAP STUDY

The Prime Study

Comparing hepatitis C care and treatment in a primary health care service with a tertiary hospital: a randomised trial

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ST VINCENT'S HOSPITAL
MELBOURNE

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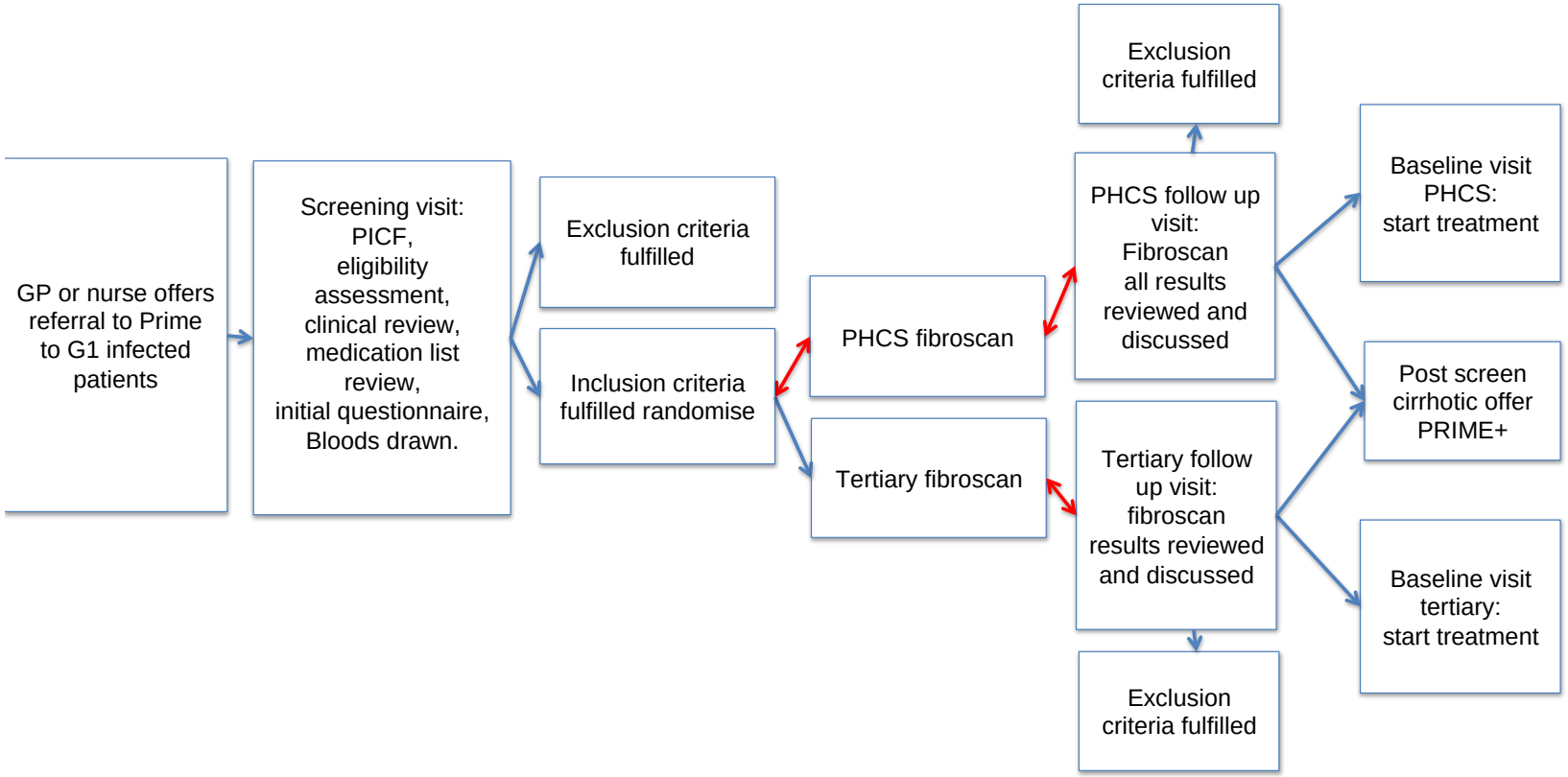
Study schedule



The Prime Study

Rationale

- The Prime study will compare treatment uptake and outcomes between people treated in Primary care and Tertiary care
- Non-cirrhotic hepatitis C genotype 1 infected patients eligible to enroll
- Treatment is all oral (significant pill burden) but highly effective, well tolerated, and 12 weeks in duration

The Prime Study

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HCV treatment as prevention in the prisons

S T O P C

Primary objective

- To evaluate the feasibility and potential impact of a rapid scale-up of IFN-free DAA HCV treatment on the incidence of HCV infection over a two year period in the prison setting

Hypothesis

- A rapid scale-up of IFN-free DAA HCV treatment in prison inmates will achieve a ≥50% reduction in the incidence of HCV infection over a two year period in the prison setting

The co EC Study

Eliminating hepatitis C transmission by enhancing care and treatment among HIV co-infected individuals.

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The co-EC Study

Rationale

- HCV DAA are Australian government subsided for all, regardless of disease stage, from 1 March 2016
- Specialists *and* general practitioners are able to prescribe DAAs
- co-EC will provide support for general practice to test and treat individuals living with HCV/HIV co-infection
- Will offer proof of concept that treating prevalent infection could reduce new primary HCV infections and re-infection

co-EC study

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The co-EC Study

Study Design

- Open label, non-randomised, clinical trial
- Clinician directed using any DAA combination approved and subsidised in Australia
- Nurse support in each clinic to support testing, patient education, assessment, and develop local capacity
- Monitoring for change in HCV testing and detections using laboratory surveillance system

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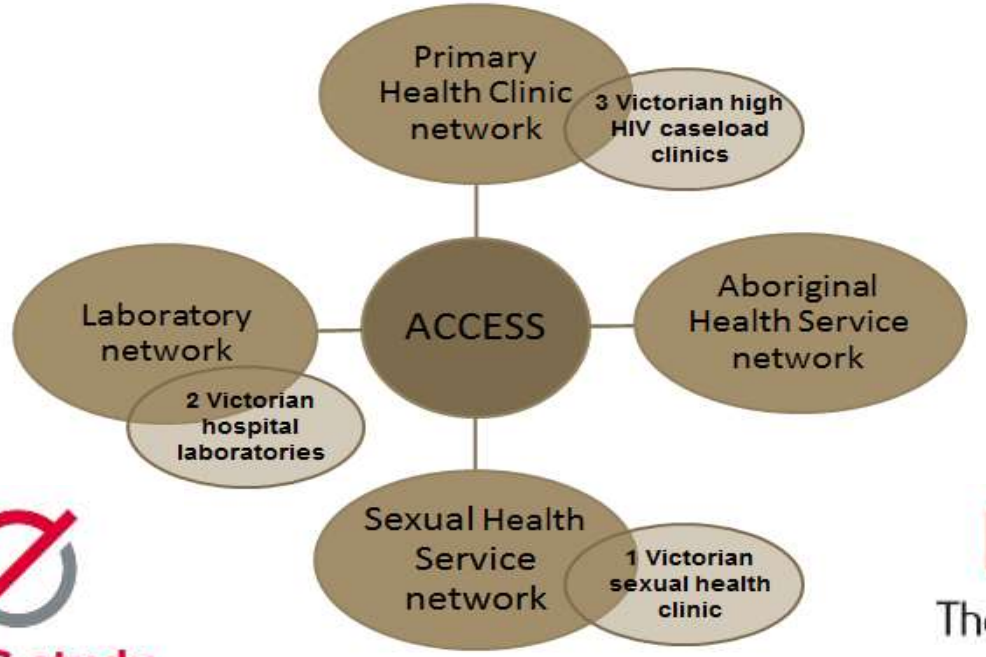
co-EC study

The co-EC Study

Study Outcomes

- Proportion commencing treatment and SVR12
- HCV incidence, reinfection incidence and prevalence using ACCESS enhanced surveillance system



co-EC study

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HCV reinfection

- HCV reinfection happens
- In non treatment cohorts – likely to be over 20%
- Post treatment – data not clear in the real world but probably between 5 - 10%
- Really simple – retreat. Benefits them and their networks
- Treat their injecting partners – a treat your friends approach
- Ensure they know about harm reduction
- There are few other diseases where we would have this conversation and have to justify this logical approach.

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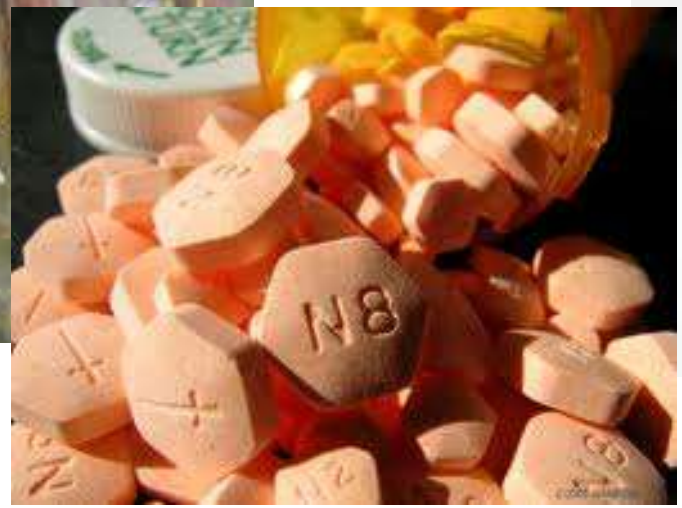
High quality, easily accessible, safe harm reduction



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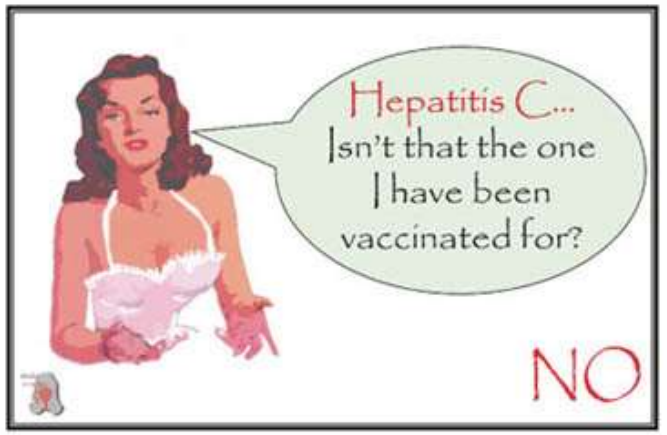
Hepatitis C Vaccine

- Epidemic varies between countries – for some a vaccine will be vital
- In some countries – unlikely to have high quality harm reduction any time soon
- Even in countries with high treatment coverage – models show HCV vaccine would be effective in stopping reinfection.



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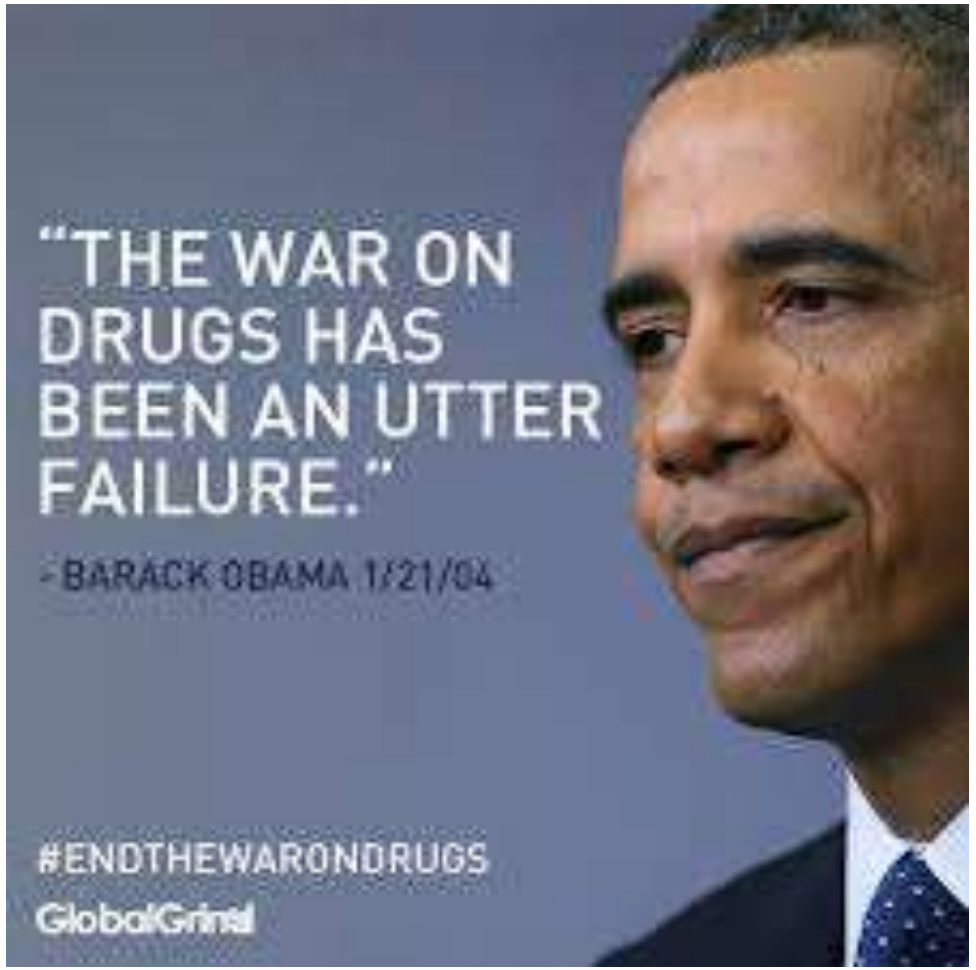
Stigma and discrimination



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The Lancet Commissions

Public health and international drug policy

Joanne Csete, Adeeba Kamarulzaman, Michel Kazatchkine, Frederick Altice, Marek Balicki, Julia Buxton, Javier Cepeda, Megan Comfort, Eric Goosby, João Goulão, Carl Hart, Thomas Kerr, Alejandro Madrazo Lajous, Stephen Lewis, Natasha Martin, Daniel Mejía, Adriana Camacho, David Mathieson, Isidore Obot, Adeolu Ogunrombi, Susan Sherman, Jack Stone, Nandini Vallath, Peter Vickerman, Tomáš Zábranský, Chris Beyrer

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S0140-6736(16)00619-X

Executive summary

In September, 2015, the member states of the UN endorsed Sustainable Development Goals (SDGs) for 2030, which aspire to human-rights-centred approaches

the same light as potentially dangerous foods, tobacco, and alcohol, for which the goal of social policy is to reduce potential harms.

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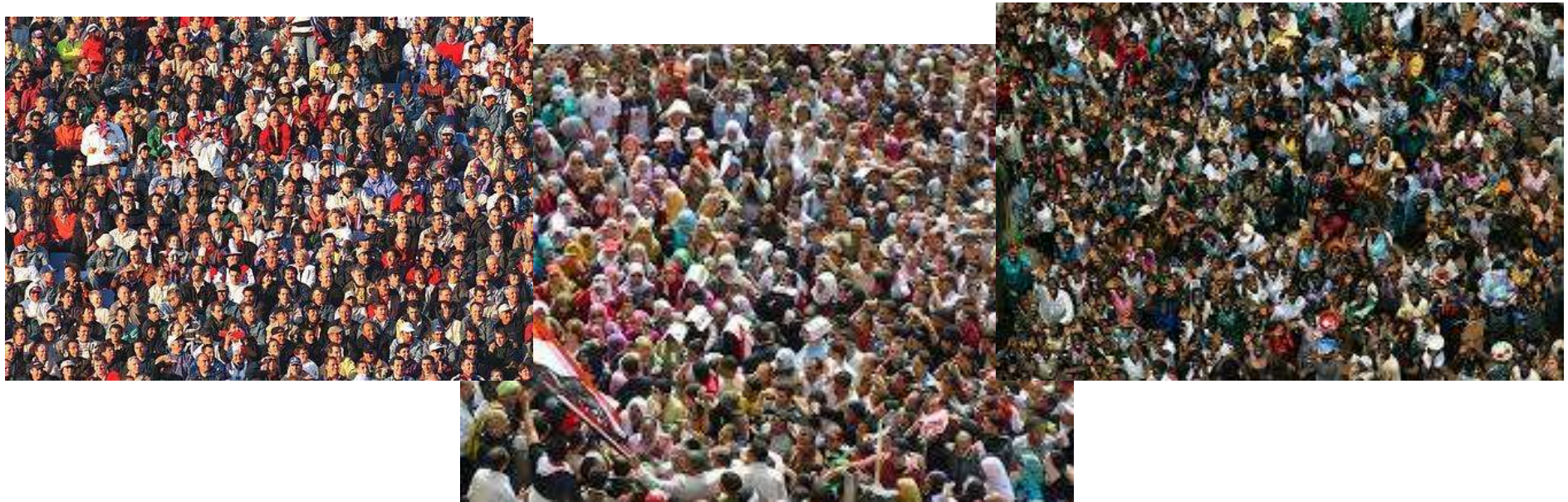
Elimination of hepatitis C

- Treat the patient in front of you, or in front of your nurse or the primary care practitioner you support or via telehealth
- Make sure you have a system of providing health care that mean all patients can be in “front of you” – particularly PWID
- Set up systems to monitor testing and treatment
- Don’t forget harm reduction



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Toronto University– Jordan Feld

WHO – Stefan Wiktor and the Viral Hepatitis team

CDC – John Ward

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