HCV: Expanding Access to Cure

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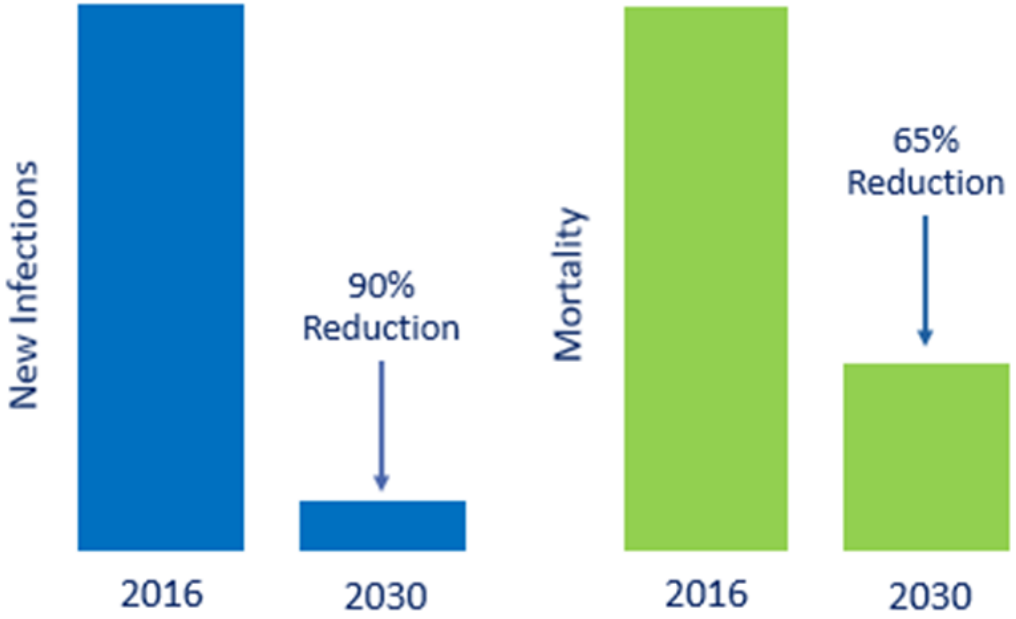
World Health Organization

Viral Hepatitis Elimination by 2030



WHO Global Hepatitis Strategy, 2016-2021.

In May 2016, the World Health Assembly endorsed the *Global Health Sector Strategy (GHSS)* on viral hepatitis 2016–2021. The GHSS calls for the elimination of viral hepatitis as a public health threat by 2030 (reducing new

- Ambitious goals
- Recent projections for US indicates we are off track by 20+ years

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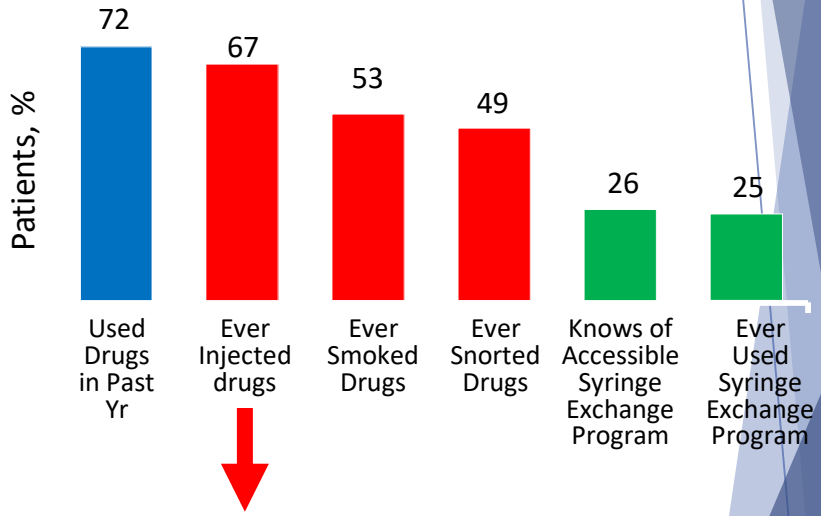
Newly Reported HCV Infections Among Individuals Age 15-29 Yrs in 8 California Counties in 2018

- **8 participating CA counties: Imperial, Lake, Monterey, Orange, Placer, Riverside, San Luis Obispo, and Santa Cruz**
  - N = 472 patients eligible
- **Responded to patient questionnaire: n = 114 (24%)**
  - Median age 26 yrs
  - 68% White
  - 48% female

Ohringer. AASLD 2019. Abstr 166.

Self-Reported Drug-Related Risk Factors Among HCV Cases Who Ever Used Any Drug (n = 61)



83% witnessed overdose
63% ever had naloxone access while injecting 44% needed naloxone during overdose but did not have it

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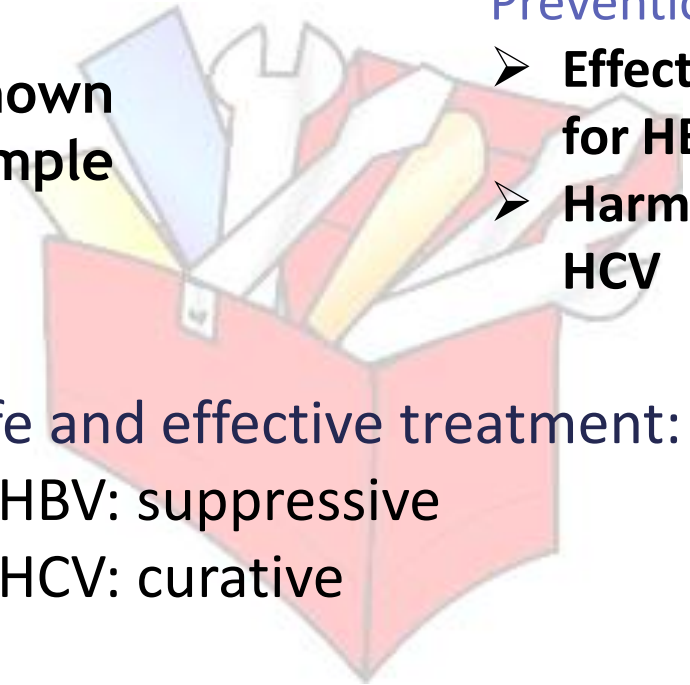
We Have the Many Tools to Achieve Elimination of HBV and HCV

Diagnosis:

- **Risk groups known**
- **Diagnosis is simple**



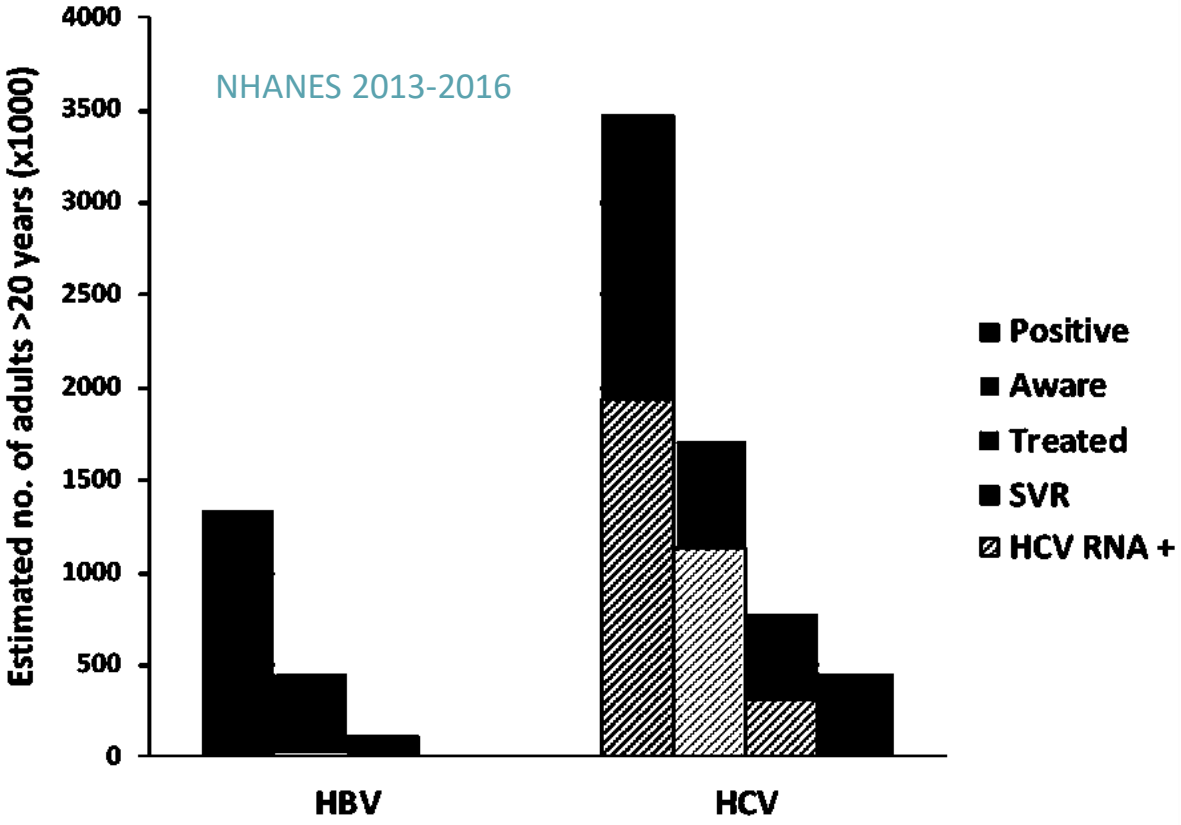
Prevention:

- **Effective, durable vaccine for HBV**
- **Harm reduction works for HCV**

Safe and effective treatment:

- HBV: suppressive
- HCV: curative

Gaps in the Cascade of Care



HBV:

- 32% aware
- 28% of aware on treatment

HCV:

- **49% aware**
- **45% of aware persons treated**
- **59% of treated patients achieved SVR**

Zhou K & Terrau

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Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

- Adults born between 1945-1965
- Risk-based:
  - IDU
  - Receipt of blood products prior to 1992 (clotting factors prior to 1987)
  - Hemodialysis
  - HIV+
  - ALT elevated
  - Recognized exposure: needlesticks, children of HCV+ moms

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA
Infectious Diseases Society of America

AASLD-IDSA

- **All pregnant women**
- **Opt-out screening in jails/prisons**

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The Second Wave of HCV in the U.S.

AASLD/IDSA: One-time screening for all persons ≥18 years of age

- ~30,000 new HCV infections per year, increasing since 2006
- Parallels the rise in opioid abuse with new consequences

California Department of Public Health. Chronic hepatitis C infections in California: cases newly reported through 2015. June 2017.

Treatment Simplification

RECOMMENDED REGIMENS*

Glecaprevir (300 mg) / pibrentasvir (120 mg)
to be taken with food for a duration of 8 weeks

Sofosbuvir (400 mg) / velpatasvir (100 mg)
for a duration of 12 weeks

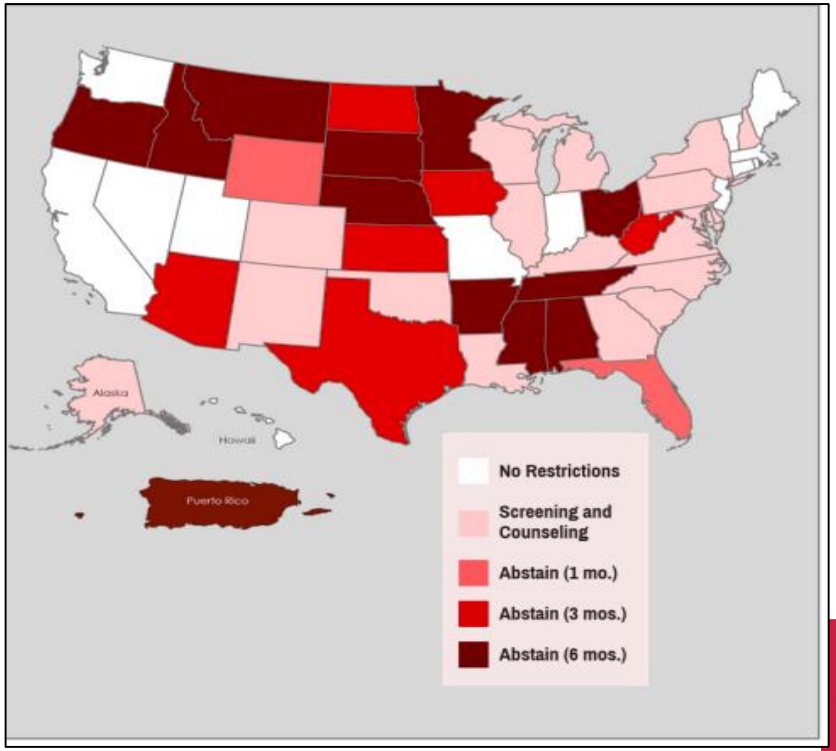
- Select based on drug-drug interactions, patient preference (pill #, packaging, # wks)
- Insurance preference

ON-TREATMENT MONITORING

- Inform patients taking diabetes medication of the potential for symptomatic hypoglycemia. Monitoring for hypoglycemia is recommended.
- Inform patients taking warfarin of the potential for changes in their anticoagulation status. Monitoring INR for subtherapeutic anticoagulation is recommended.
- No laboratory monitoring is required for other patients.
- An in-person or telehealth visit may be scheduled, if needed, for patient support, assessment of symptoms, and/or new medications.

Patients Using Drugs/Alcohol Denied Access to HCV Treatment in Some States

- Medicaid reimbursement criteria for DAAs based on required drug/alcohol abstinence period
- In California, this should not be a barrier to accessing HCV treatment



CHLPI CENTER for HEALTH LAW and POLICY INNOVATION HARVARD LAW SCHOOL

NVHR National Viral Hepatitis Roundtable

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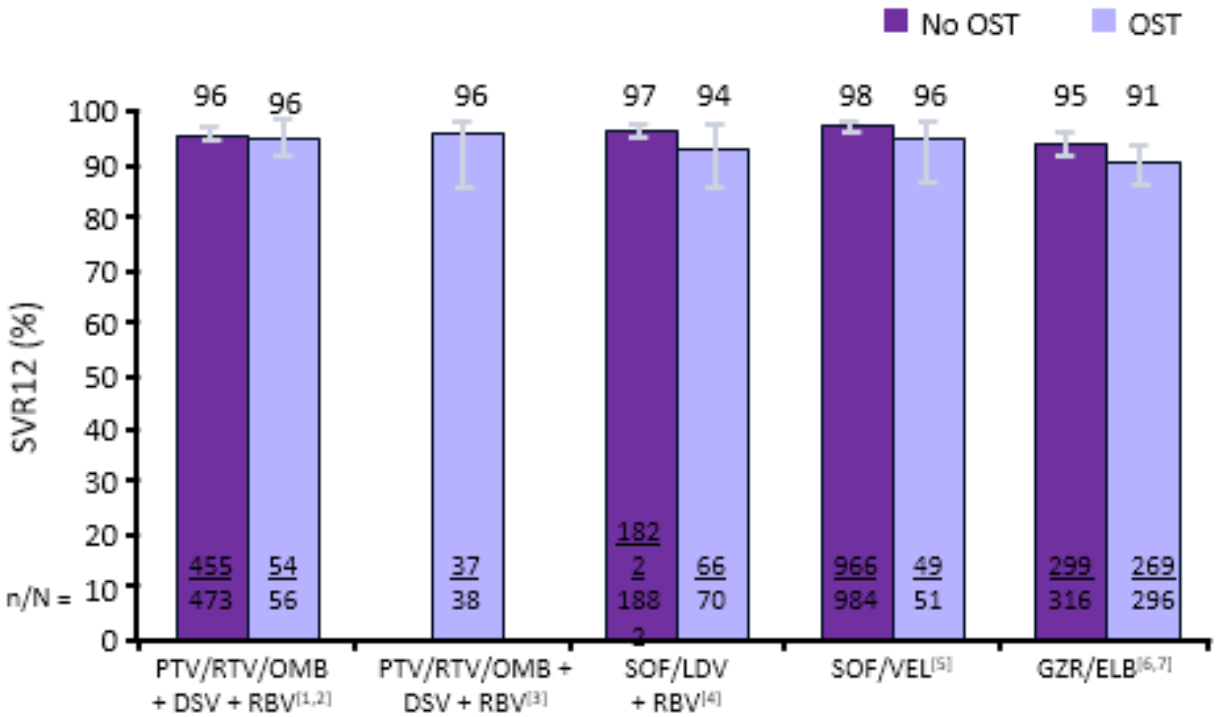
DAA Therapy in PWID: OST vs Non-OST



In clinical trials:

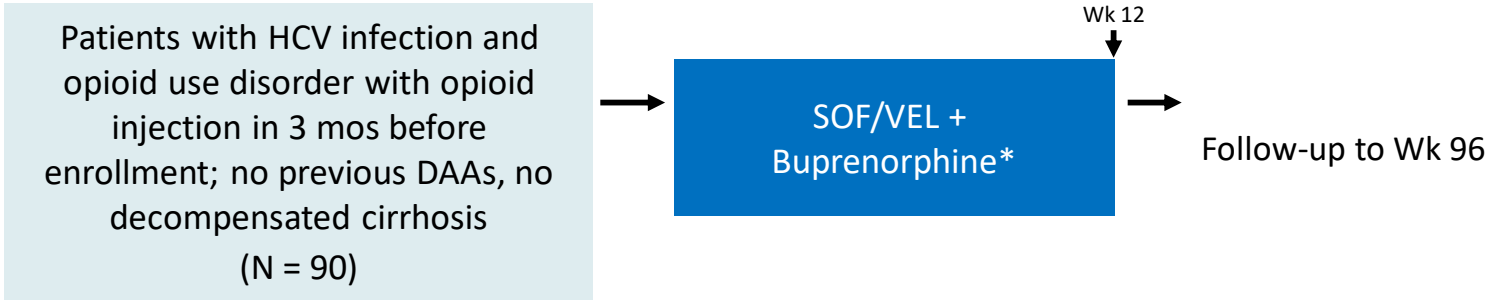
Rates of SVR are comparable in patients on OST and those not

OST: opiate substitution therapy

Feld JJ, et al. N Engl J Med. 2014; Puoti M, AASLD 2014; Lalezari J, J Hepatol. 2015; Grebely J, Clin Infect Dis. 2016; Zeuzem S, Ann Intern Med. 2015; Dore GJ, Ann Intern Med. 2016.

ANCHOR Substudy: Colocation of HCV and Buprenorphine Treatment

- **Substudy of single-arm HCV treatment trial in Washington, DC**
  - **Endpoints: adherence to SOF/VEL, SVR12 rate; risk behaviors, HCV reinfection, HIV acquisition**



*Buprenorphine started between Wk 0-24 of SOF/VEL treatment initiation with follow-up for 1 yr at same center and with same provider as HCV treatment.

Rosenthal E, et al. EASL 2018. Abstract PS-092.

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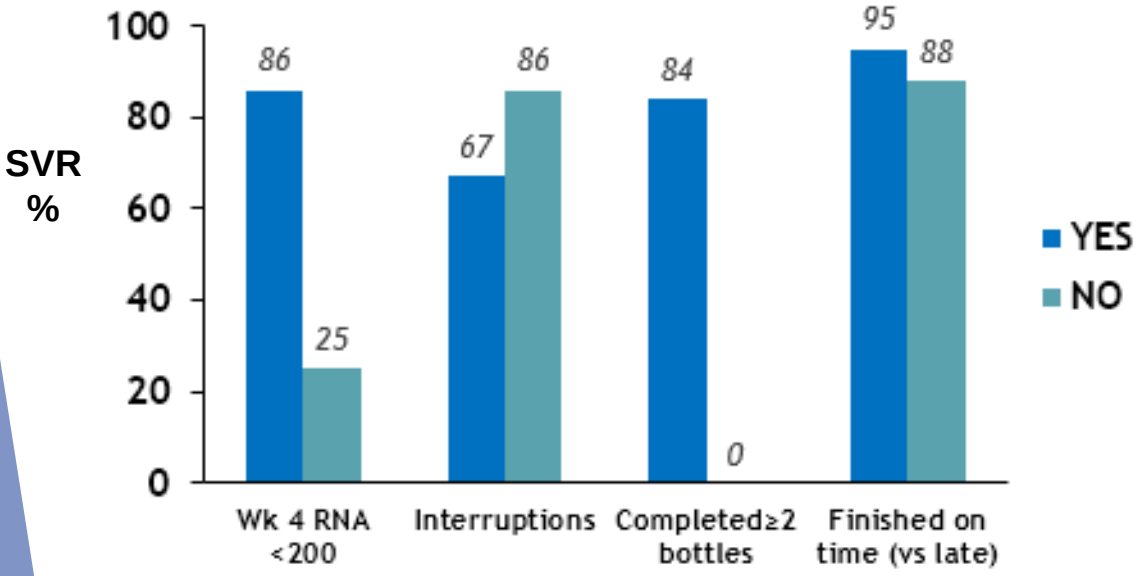
Anchor Study: SOF/VEL in PWIDs

Active injection drug use within 3 m treated with SOF/VEL x 12w, n=66

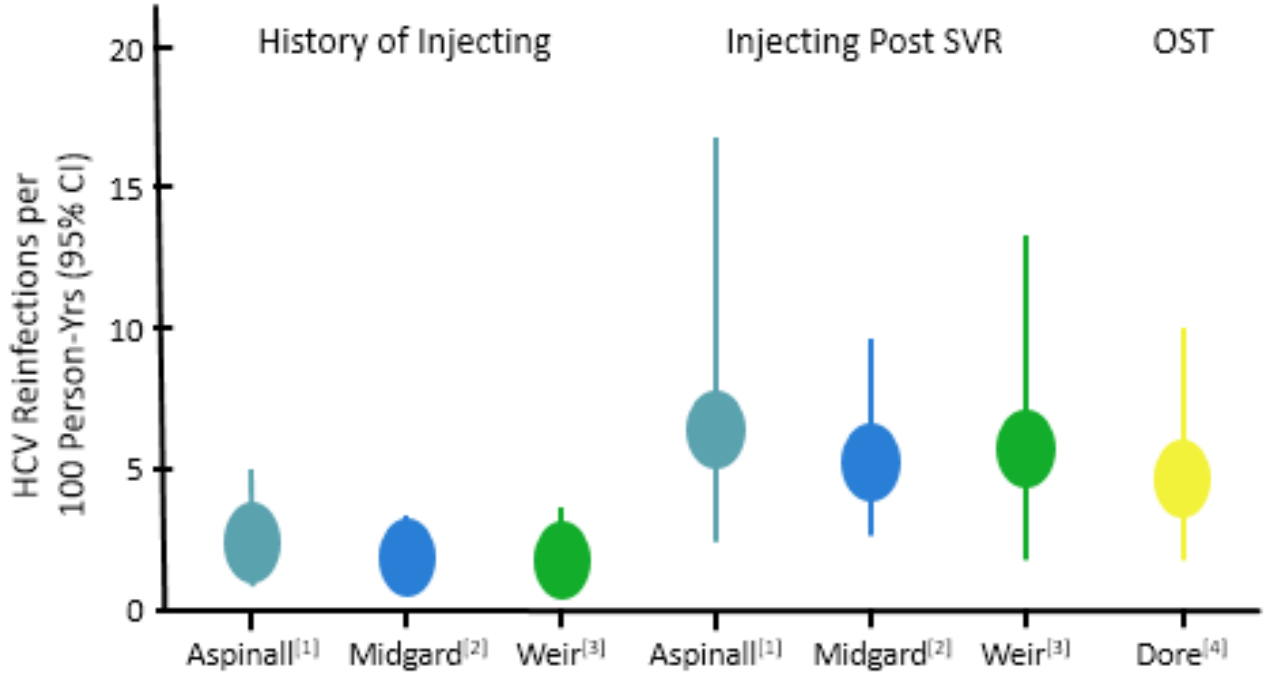


- 78% achieved SVR
- **SVR lower if:**
  - HCV RNA>200 IU/mL at week 4
  - <8 weeks of therapy total
- Finishing late – even 14d late – no effect on SVR

- High SVR rates despite imperfect adherence
- **Missed doses and finishing late had little effect on SVR**

y et al AASLD 2018, Abstract 18

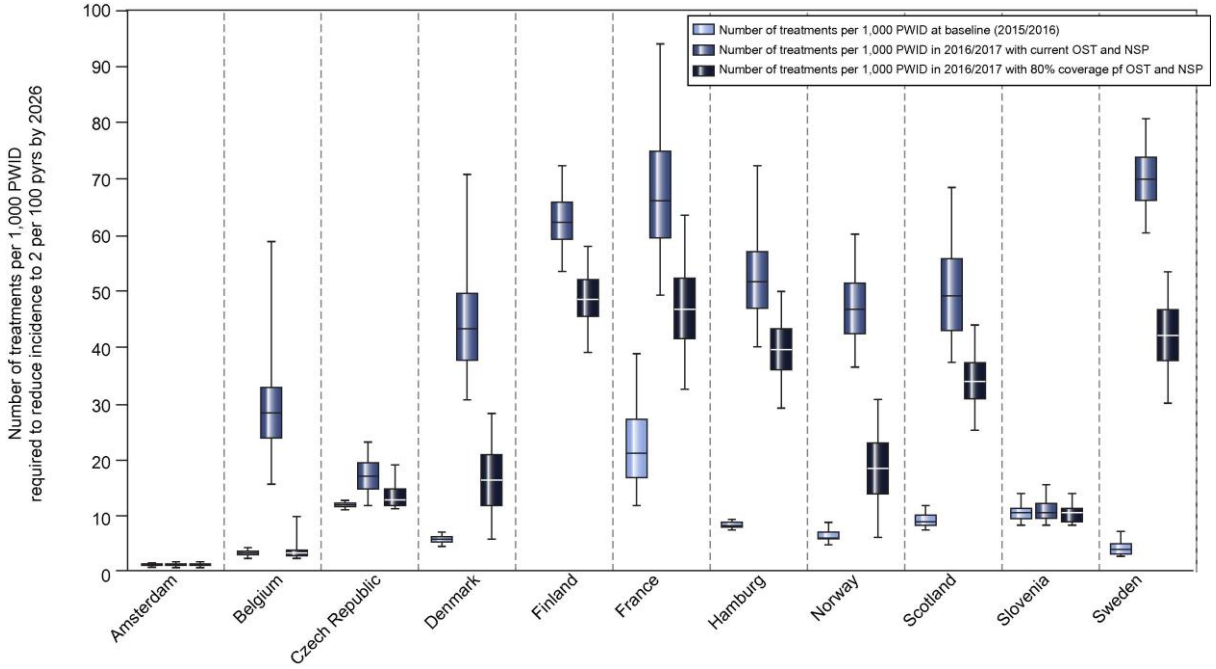
HCV Reinfection by Study Population



"If there are no cases of reinfection, then you are not treating a current PWID population"

1. Aspinall EJ, et al. Clin Infect Dis. 2013 2. Midgard H, et al. International Liver Congress 2015;3. Weir A, et al. Drug Alcohol Depend. 2016;4. Dore GJ, et al. Ann Intern Med. 2016.

Maximum Reductions in New HCV Infections if Treatment Partnered with Harm Reduction



Fraser H, J Hepatol, 2018:68:402-411

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Specific Issues of Treating HCV in PWIDs

- **High priority group for the "treat to prevent transmission" strategy**
- **Rapid scale-up:** A slow scale-up will create HCV "susceptible" PWID without reduction in viremic pool
- **Co-management is highly desirable:** HCV and drug use disorder
- **SVR rates are acceptable** - comparable to non-PWIDs **-- as long as the total treatment course is completed.**
- **There will be cases of HCV reinfection:** be prepared to retreat
- **Harm reduction optimization (SSP, OST access) is important:** to reduce reinfections and new infections

Summary of HCV Management

- ~50% undiagnosed → universal screening recommended
- Treatment is simplified with 2 pan-genotypic regimens
  - ≥95% cured with initial treatment
- For persons who inject drugs, important to couple HCV treatment with harm reduction
  - Colocalization of care best model
  - HCV cure rates in PWIDs on or off OST are similar – key is completion of treatment
- Care after cure
  - Counsel to reduce risk of infection and maintain good liver health

Thank-You!

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