

# Challenges Faced With HCV Screening and Linkage to Care/Treatment

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# Disclosure

- I am a principal investigator of an ANTHC sponsored sofosbuvir-based treatment study of Alaska Native/American Indian persons. This study was funded in part by Gilead Sciences.

## Pre-Talk Question

How many people does 1 untreated person with hepatitis C who injects drugs infect within first 3 years of initial infection?

- a. 1-5
- b. 6-10
- c. 11-15
- d. 16-20
- e.  $\geq 21$

# Objectives

Recognize status  
of HCV screening  
and treatment  
within the ATHS

Raise awareness  
about Hepatitis C  
in 2023

Discuss challenges  
faced with HCV  
screening and  
treatment

# Basic Facts About Hepatitis C in 2023

- Hepatitis C is a virus that attacks the liver and causes inflammation
- It can lead to cirrhosis, liver cancer, and liver failure over time
- Hepatitis C can be cured by taking 1-3 pills for 8-12 weeks; the medications to treat it have few side effects and have a 95% - 100% cure rate
- 40% of people living with hepatitis C are unaware that they have it
- Simplified Treatment is recommended now:  
<https://www.anthc.org/what-we-do/clinical-and-research-services/hep/hep-c-treatment-information/>
- No substance use restrictions for Hep C treatment

# What Has Happened Between the Start of DAA Treatment and Present?

## Progress

- Price of HCV drugs decreased
- Medicaid restrictions went away
- PA requirements decreased
- Universal screening guidelines were released 2020

## Challenges

- 40% of people with hepatitis C are unaware that they are infected
- Opioid – Hepatitis C Syndemic
- COVID setbacks – outreach programs underfunded, staffing cut
- Number of persons treated per year for hepatitis C decreased

MMWR 71, August 12, 2022/71(32);1011-1017 available at:

[https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e1.htm?s\\_cid=mm7132e1\\_w](https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e1.htm?s_cid=mm7132e1_w)



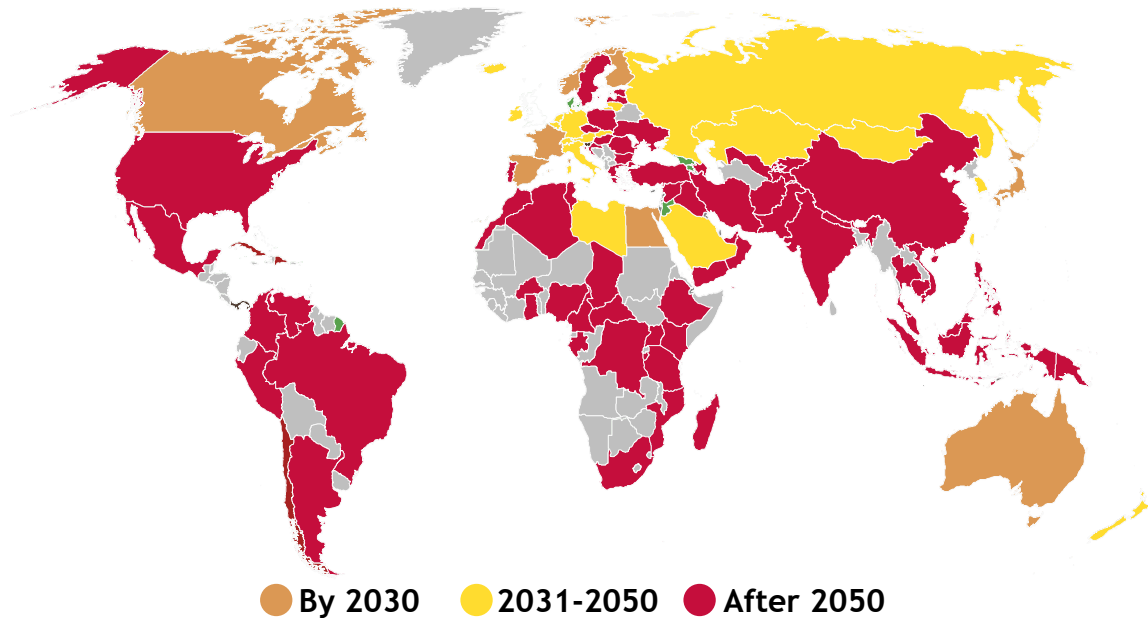
# Evaluation of Global Progress Towards HCV Elimination

Analysis of Polaris Observatory 2022 preliminary elimination estimates and results of a policy survey

## HCV Targets

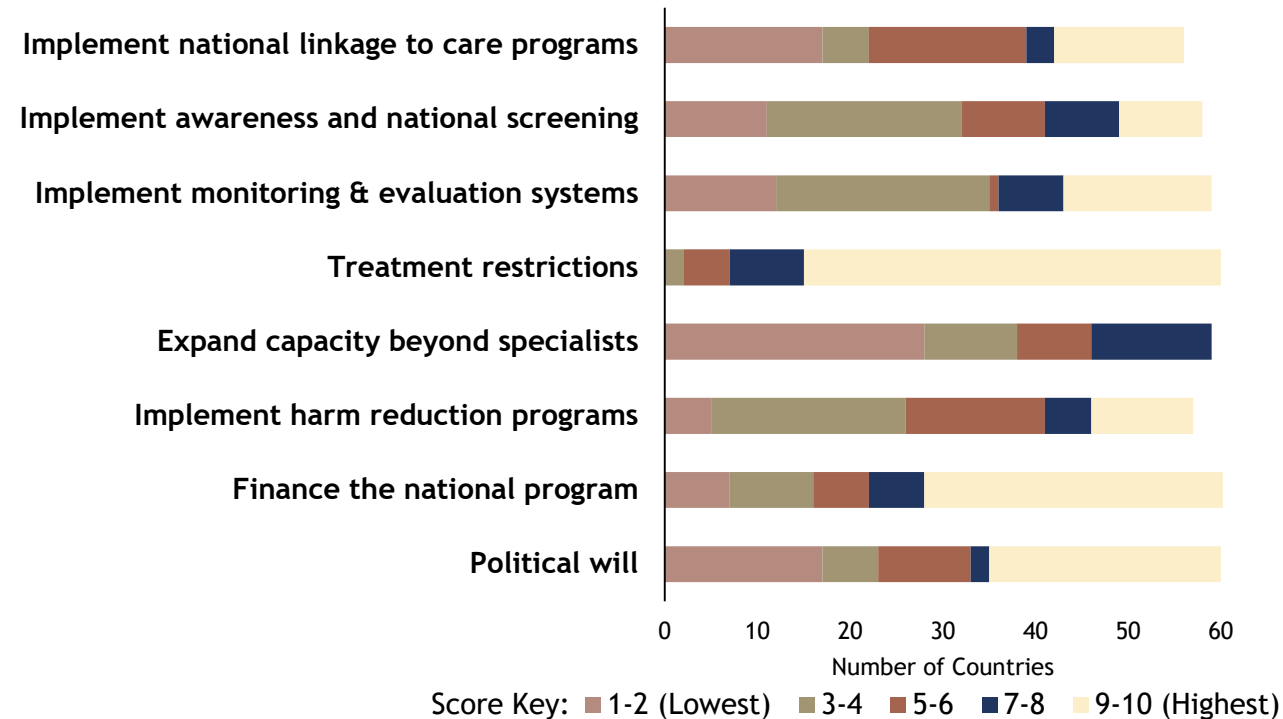
80% reduction in incidence, 65% reduction in mortality,  
90% diagnosed, 80% of diagnosed are treated

## Year of Achieving HCV Elimination Targets



11 countries are on track to achieve HCV elimination targets,  
more work is required in expanding treatment beyond specialists

## Qualitative Policy Assessment (2020 and 2022)



# How are we doing in the ATHS?

- >1200 persons treated
- Training Programs to Build Capacity
- Providers following the Simplified Treatment Model
- Robust screening and treatment program CAIHC
- Successful Pharmacist led treatment initiative at SCF
- SEARHC has made HCV screening a 2023 quality measure

Wins

Still 1200 people untreated

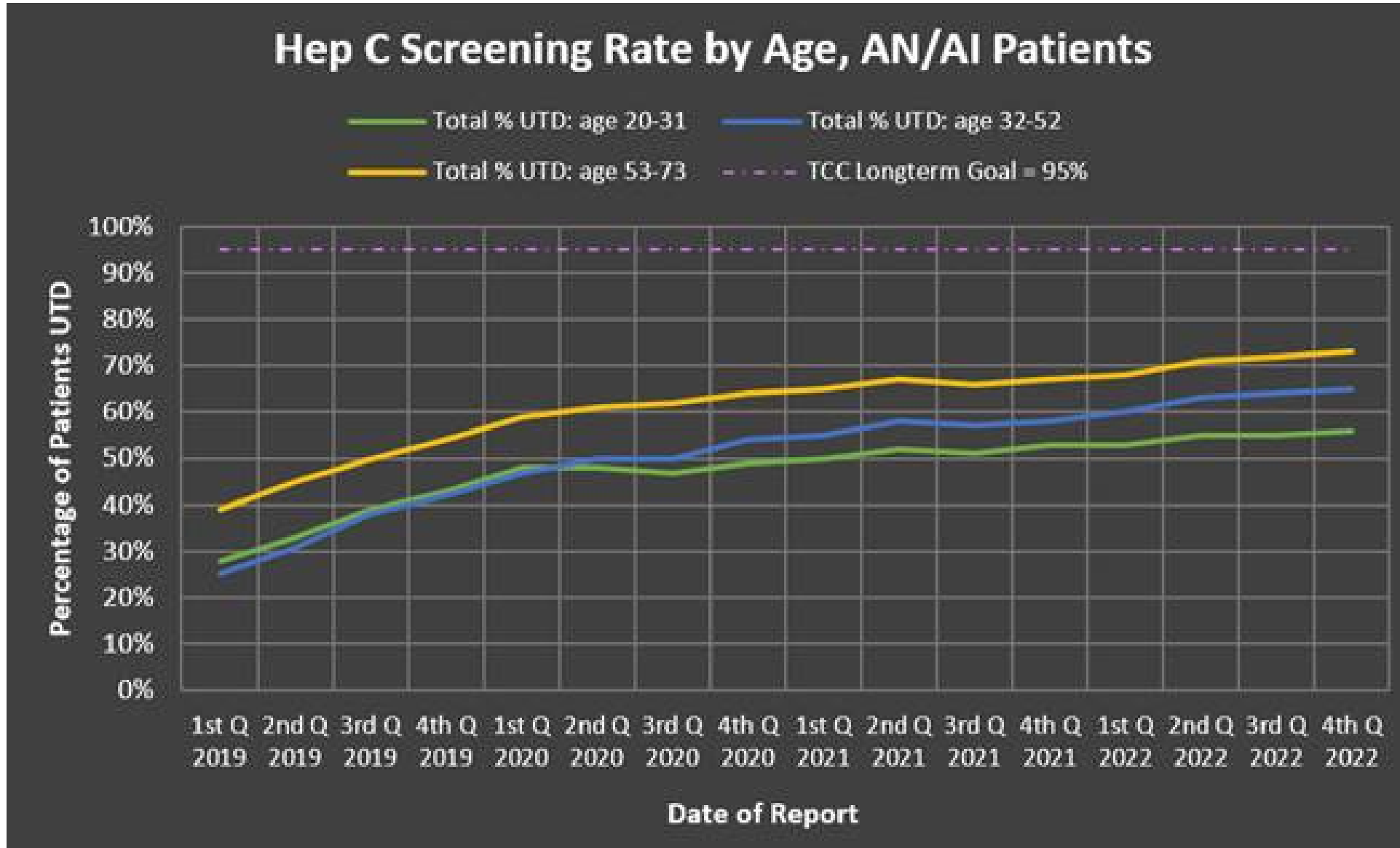
Estimated 2000-3000 persons not yet diagnosed

So we have a ways to go to get to an elimination goal of 90% of persons with hepatitis C diagnosed and treated/cured

Existing Challenges

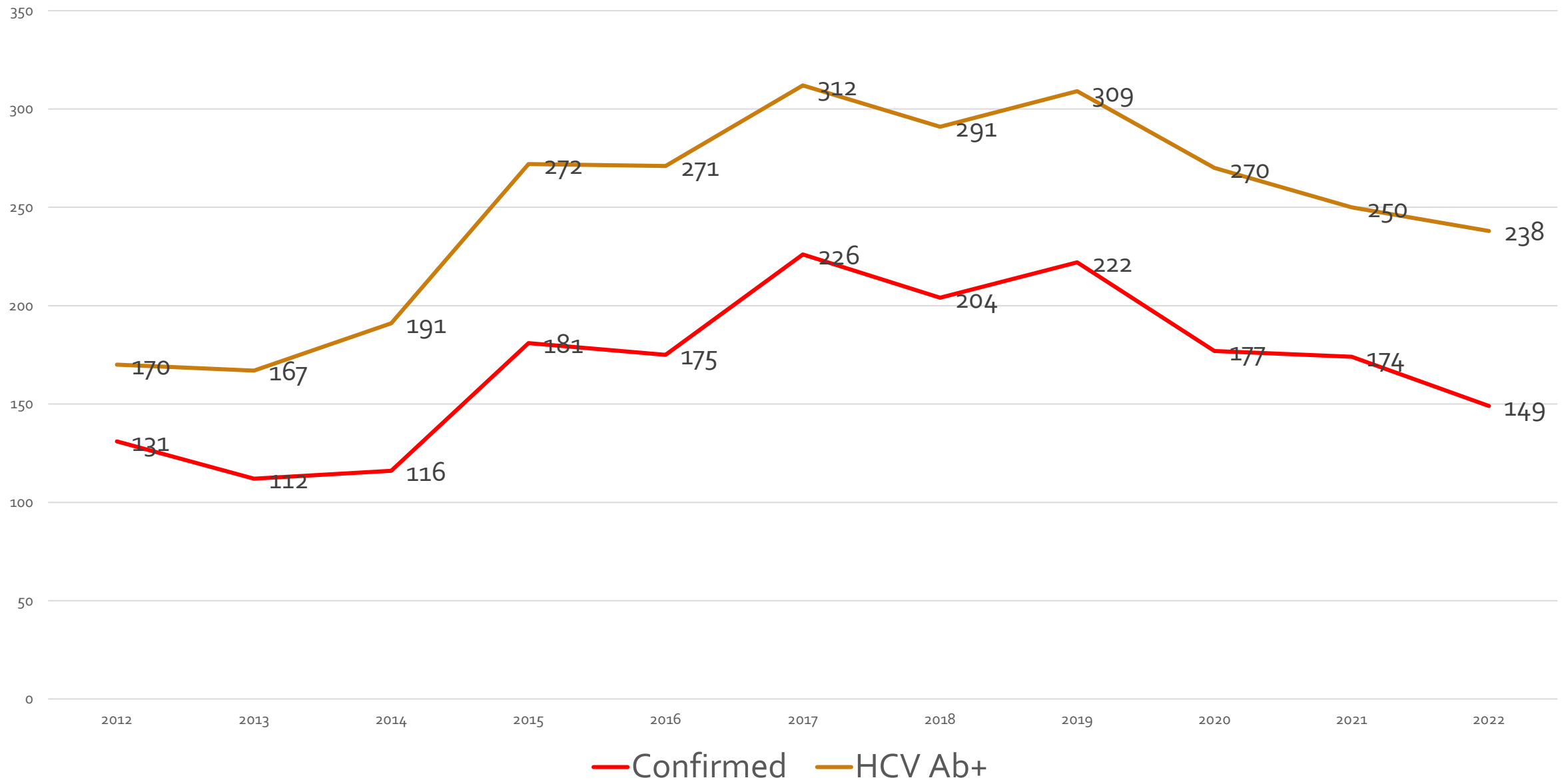


# TCC HCV Screening Program

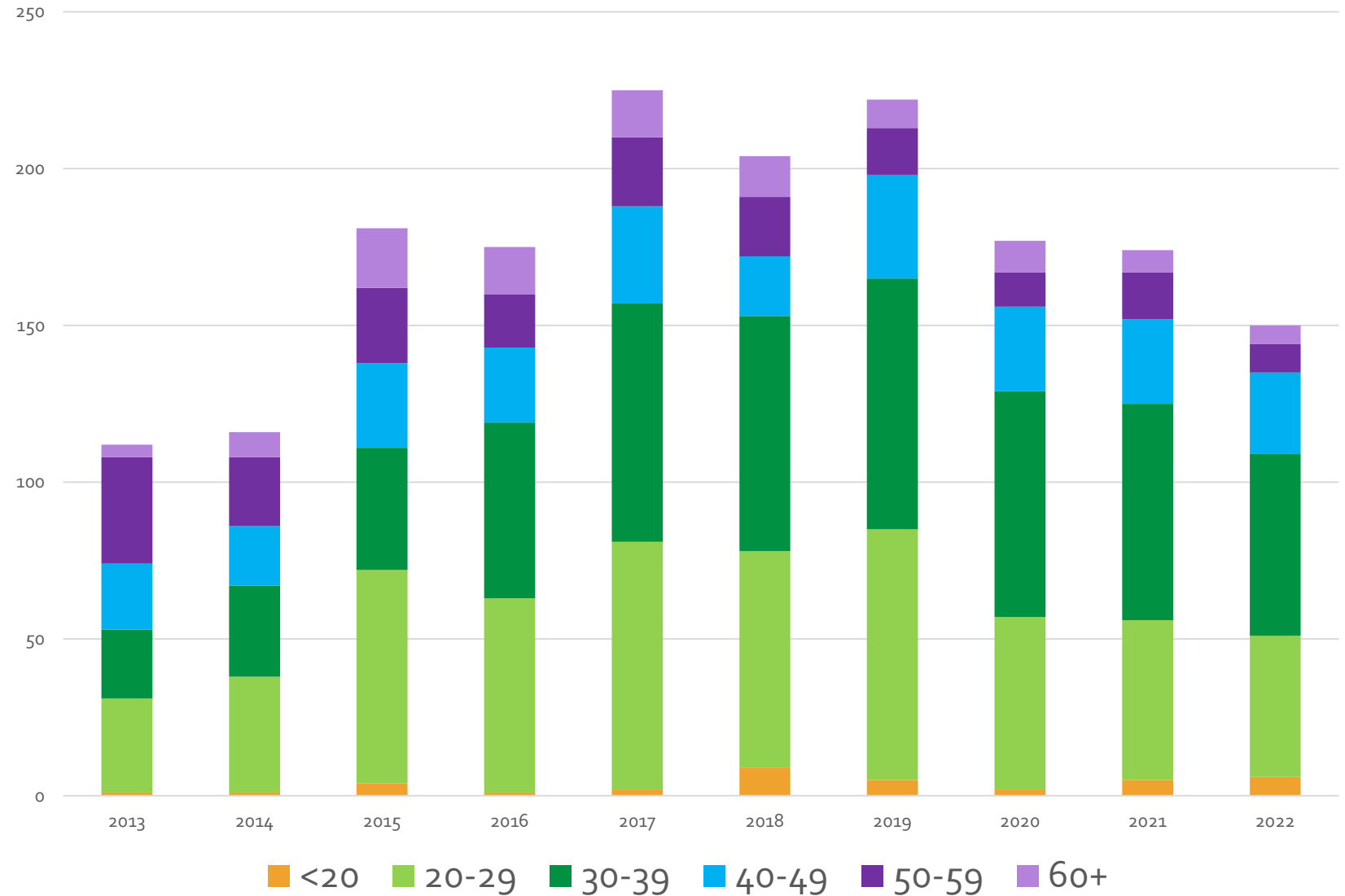


Slide provided by  
Stephen Gerrish, MD  
Tanana Chiefs  
Conference

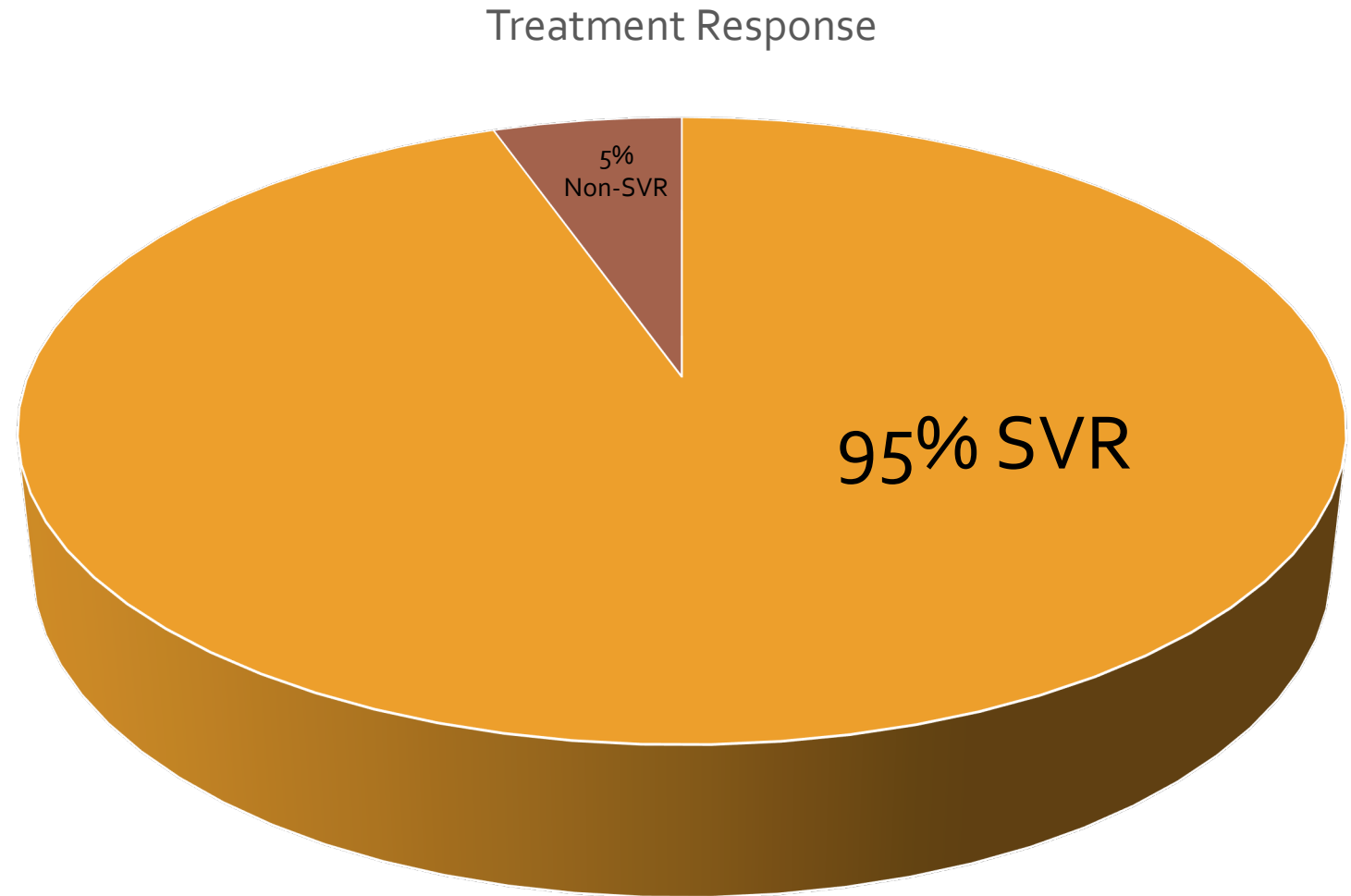
# New Cases of Hepatitis C 2012-2022



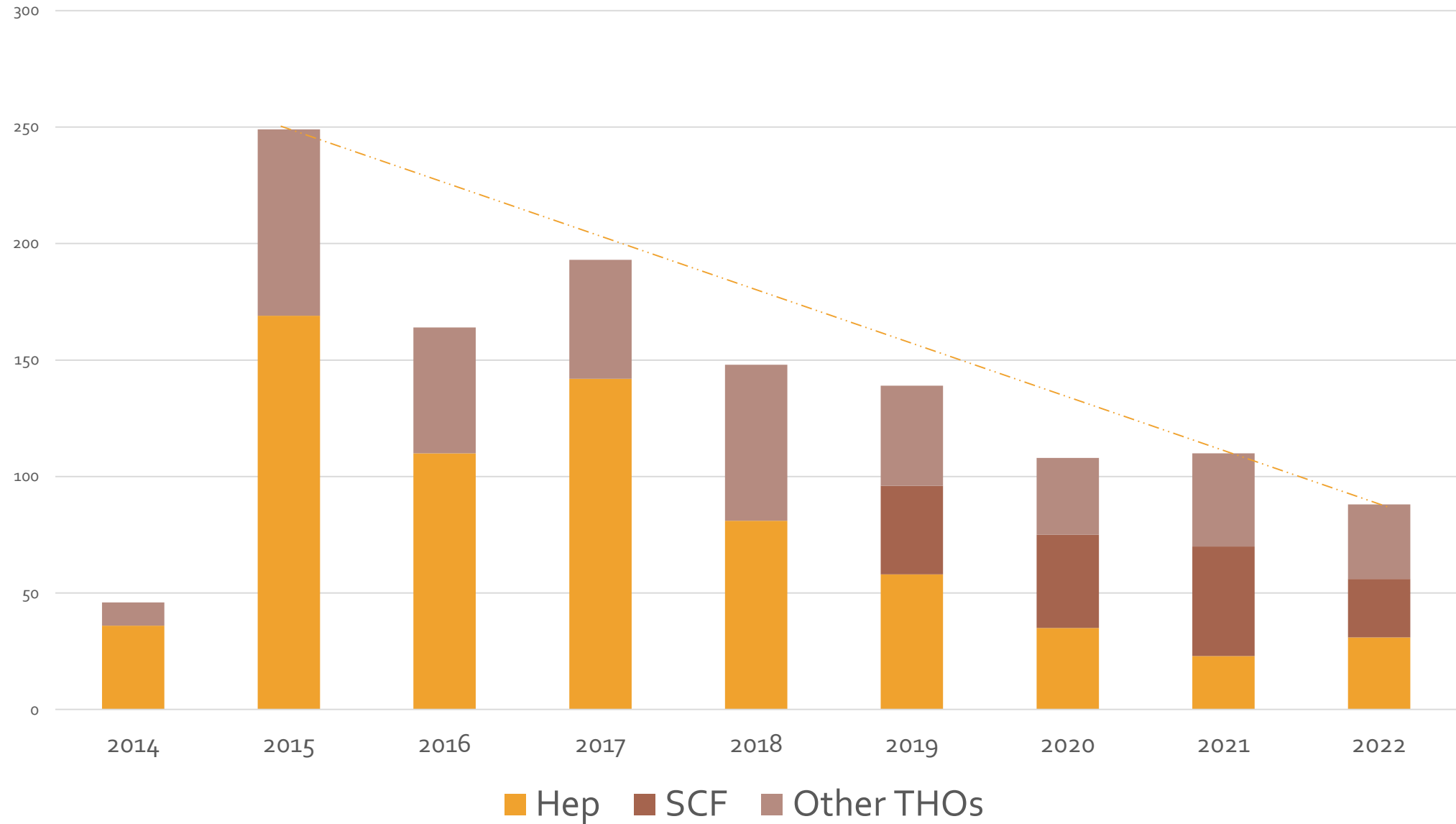
# Age Breakdown of those Confirmed with Hepatitis C



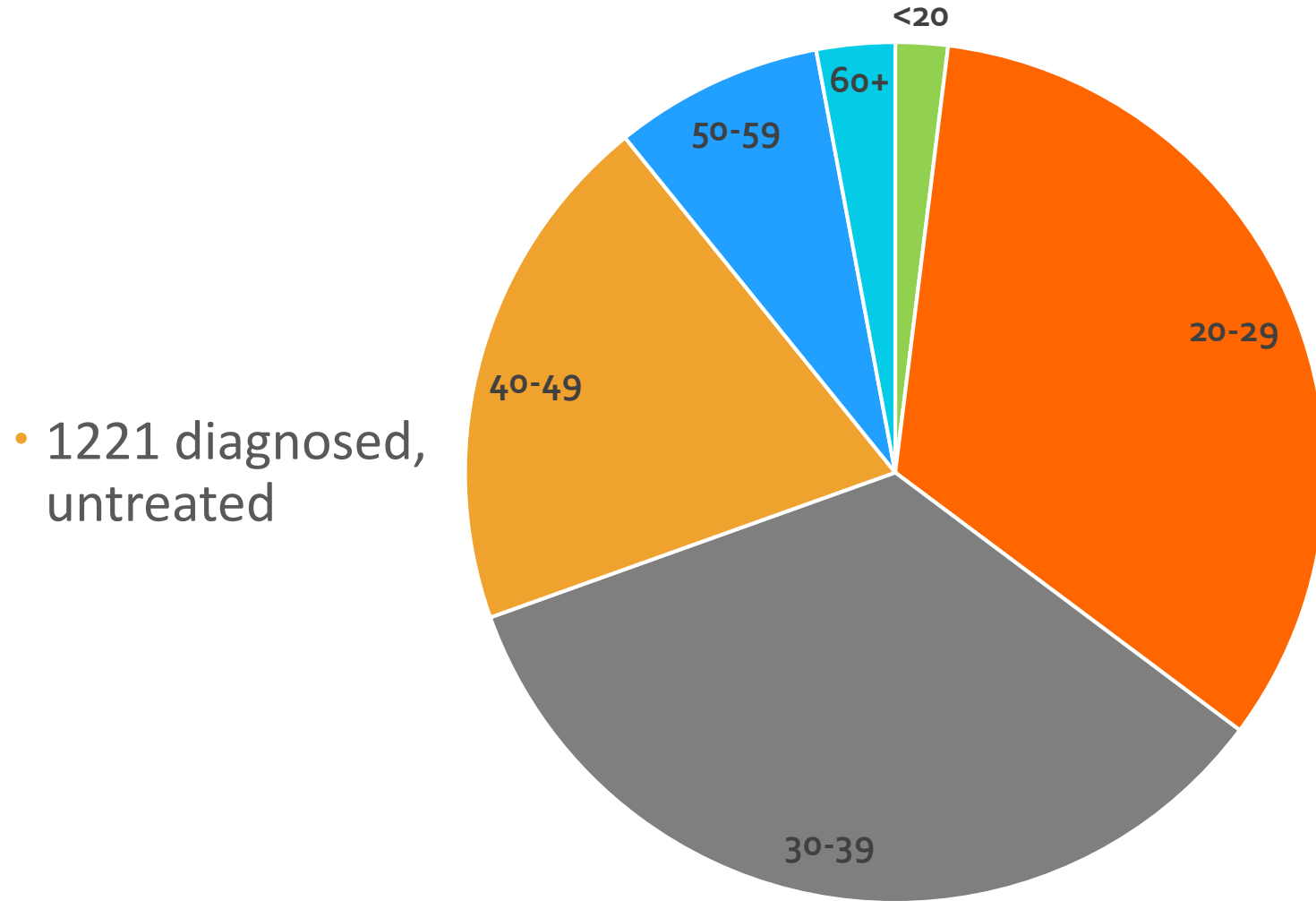
# Hepatitis C Treatment Response Among AN/AI Persons in the Alaska Tribal Health System



# Hepatitis C Treatment 2014 to Present ATHS

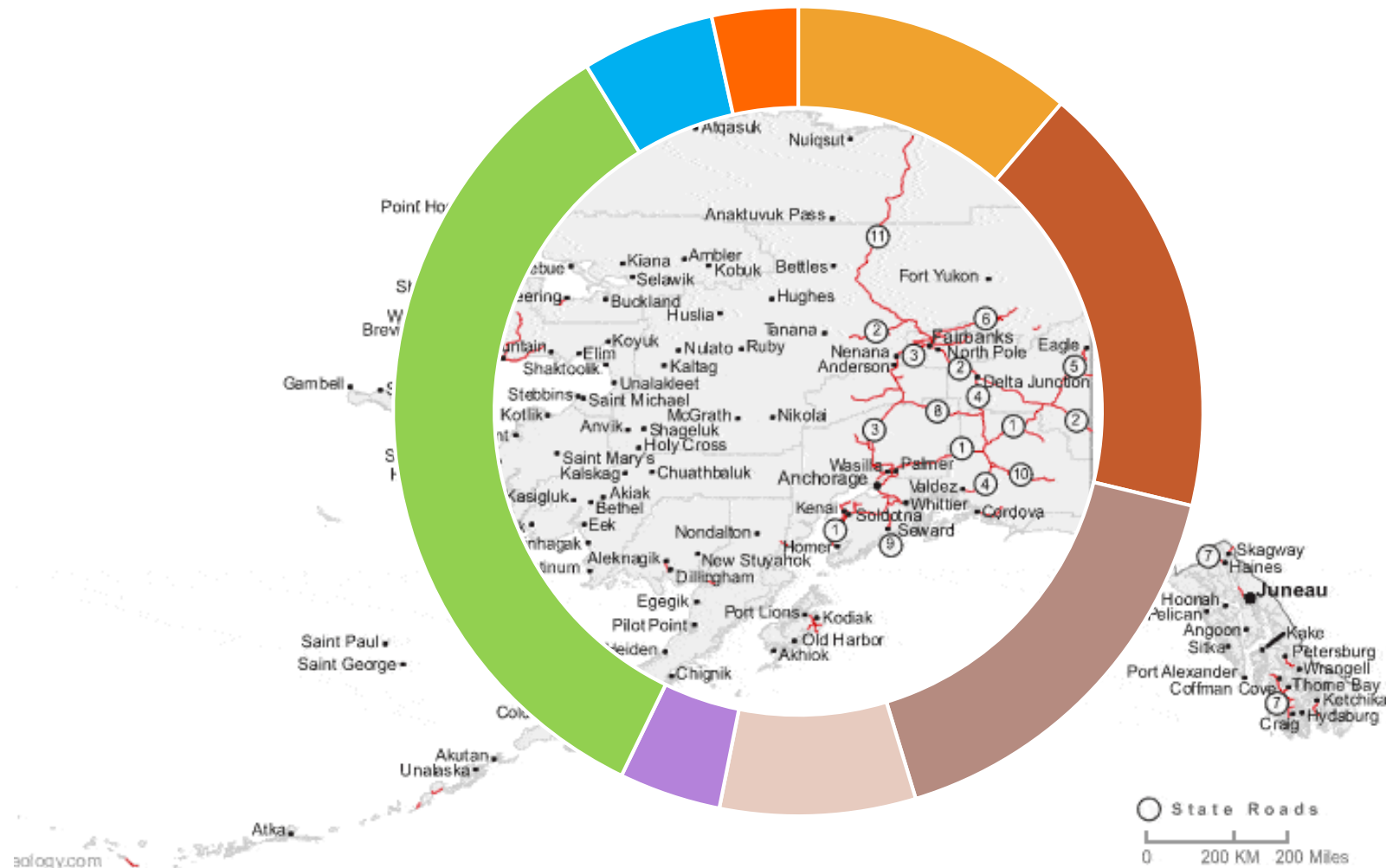


# Age Range of Untreated



# Untreated Hepatitis C - Outside Anchorage Service Unit

■ Bethel ■ Dillingham ■ Fairbanks ■ Ketchikan ■ Kotzebue ■ Mt. Edgecumbe ■ Nome ■ Utqiagvik



# Who Remains To Be Treated

- Unscreened/undiagnosed across the age spectrum
- Pregnant women – STORC clinical trial ongoing – NCT05140941
- Children – Sof/Vel and Gle/Pib approved age 3+, pellets
- Hard to Reach Populations
  - PWID
  - Persons who do not routinely see a primary care provider
  - May be homeless or unstable housing
  - Justice involved



# Why Treat Hepatitis C?

Treatment is prevention

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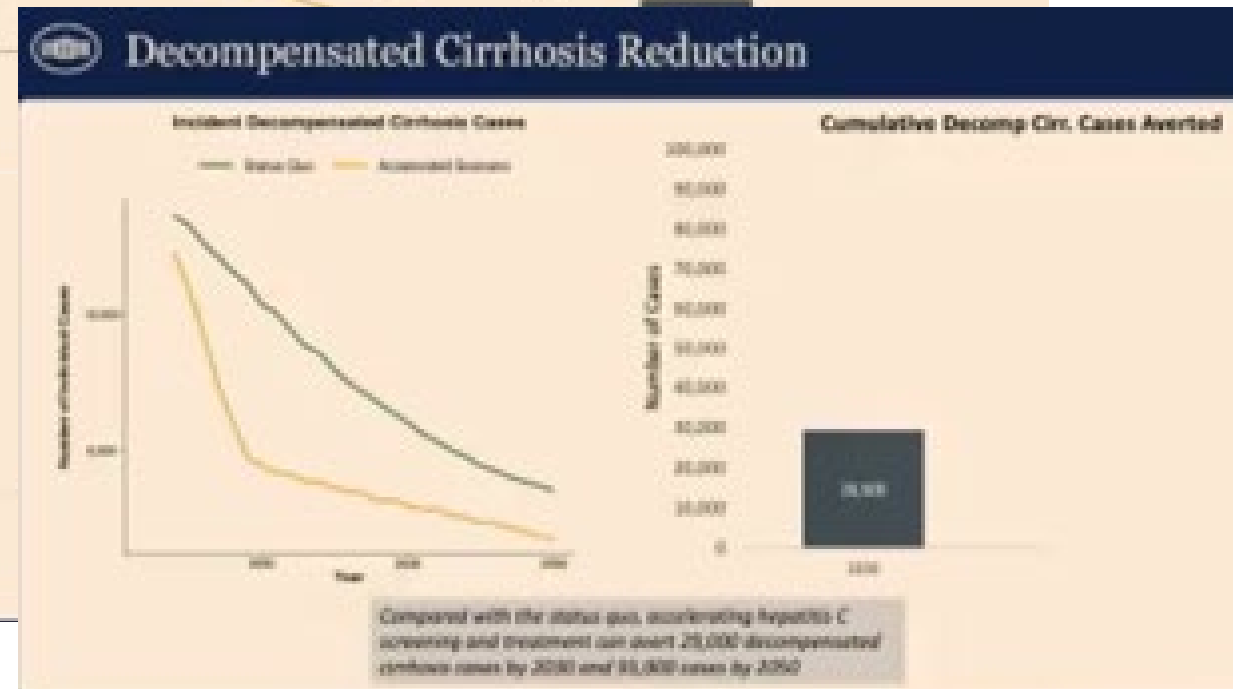
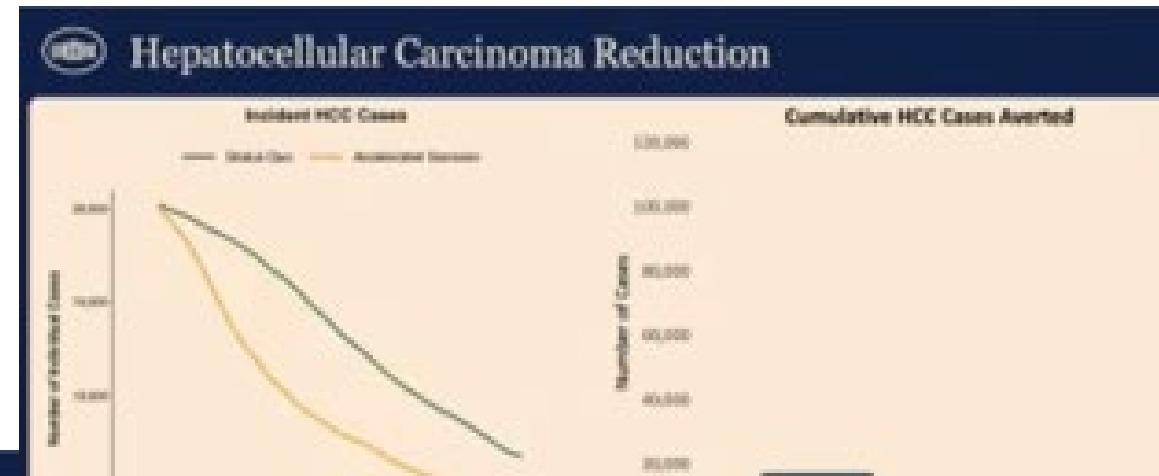
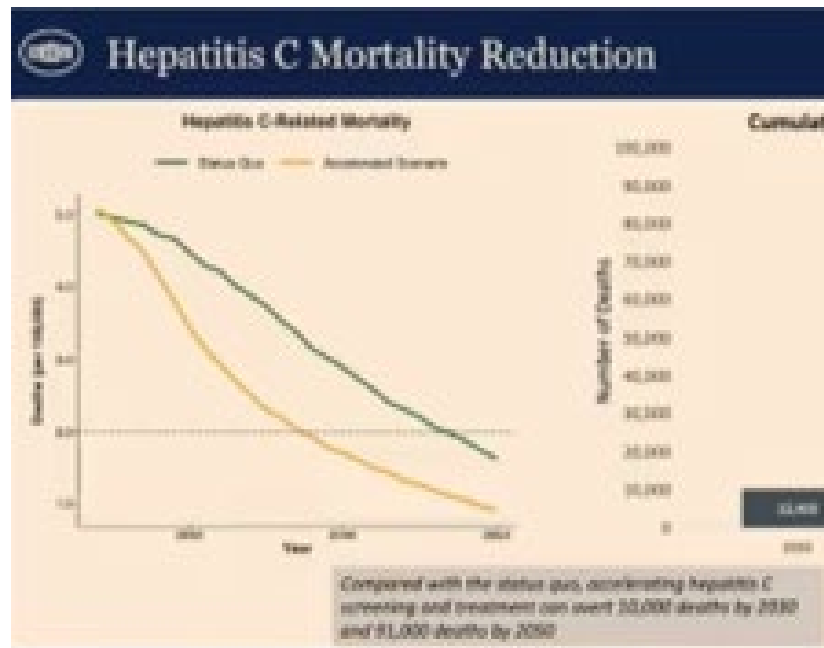
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# Treatment is Cost Saving

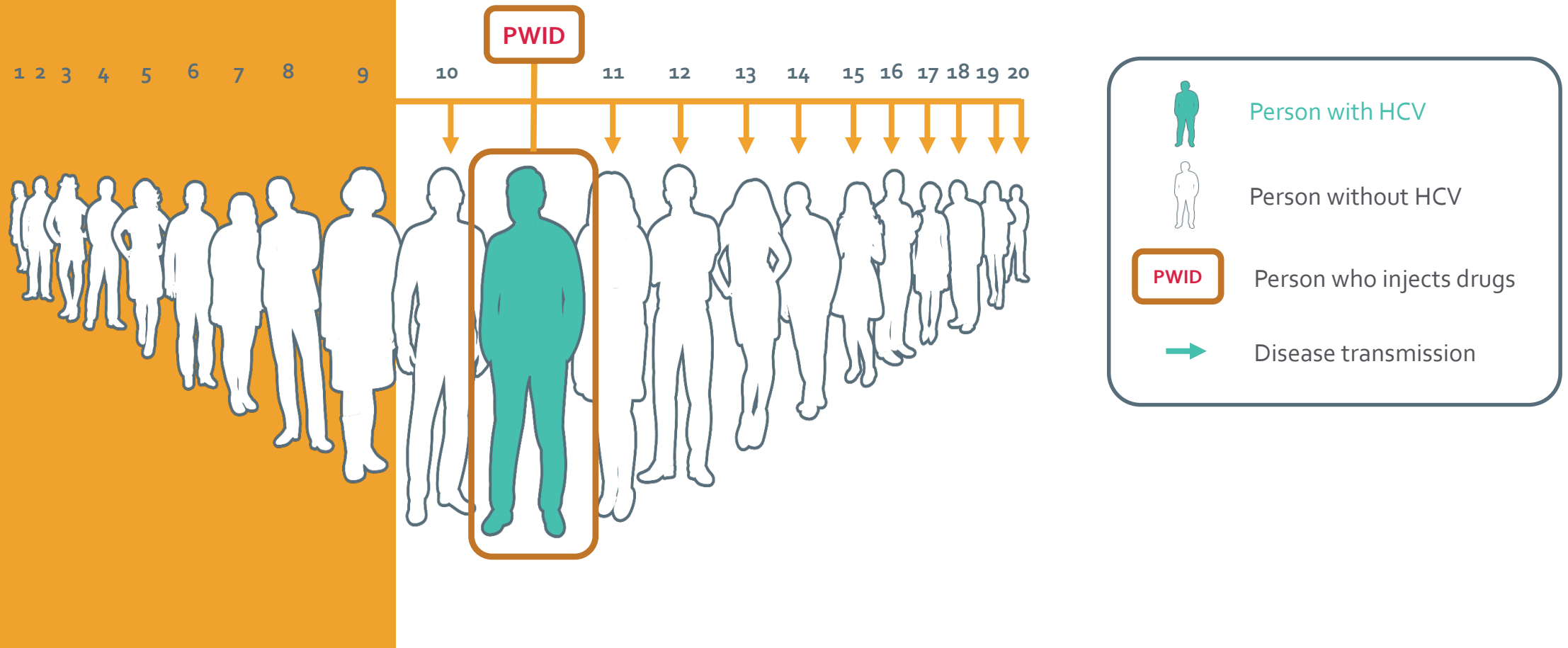


Chhatwal, J et al. Estimation of HCV Disease Burden and Budget Impact of Treatment Using Health Economic Modeling; Inf Dis Clinics of NA; June 2018 32(2):461-480



# Why Treat Persons Who Inject Drugs?

# EACH PWID WITH HCV IS LIKELY TO INFECT 20 OTHER PEOPLE WITHIN THE FIRST 3 YEARS OF INITIAL INFECTION<sup>1,2</sup>



NIH=National Institutes of Health.

1. NIH National Institute on Drug Abuse. Updated June 2021. Accessed November 2, 2021. <https://www.drugabuse.gov/download/37596/heroin-research-report.pdf>
2. NIH National Institute on Drug Abuse. Updated August 3, 2020. Accessed November 9, 2021. <https://www.drugabuse.gov/drug-topics/viral-hepatitis-very-real-consequence-substance-use>

# Simplify Study

## SIMPLIFY STUDY DESIGN

- An open-label, Phase 2 clinical trial (N=103)<sup>1</sup>
- Evaluated the efficacy, safety, and adherence of EPCLUSA in GT 1-4, NC/CC, HCV-infected PWID, including patients on MAT for opioid use disorder (N=58)<sup>1</sup>
- Patients received EPCLUSA in weekly blister packs for 12 weeks<sup>2</sup>

## INCLUSION CRITERIA<sup>2</sup>

- Adult HCV-infected PWID, defined as self-reported injection drug use within the previous 6 months
- Patients without cirrhosis and with compensated cirrhosis
- Treatment-naïve and treatment-experienced<sup>a</sup>

## EXCLUSION CRITERIA<sup>2</sup>

- HIV infection
- Decompensated liver disease

## PRIMARY ENDPOINT<sup>1,3</sup>

- SVR12 (cure), defined as HCV RNA <LLOQ 12 weeks after treatment completion

## KEY SECONDARY ENDPOINT<sup>2</sup>

- Adherence, assessed by dividing the number of total doses received by total doses expected (84)

CC=compensated cirrhosis; NC=non-cirrhotic; NS5A=nonstructural protein 5A; QD=once daily; VEL=velpatasvir.

<sup>a</sup>TE patients were naïve to NS5A-based HCV therapy.

**1.** EPCLUSA US full Prescribing Information. Gilead Sciences, Inc. Foster City, CA. April 2017; 2. Grabovsky, et al. *Lancet Gastroenterol Hepatol*. 2017;3(1):33-41. 3. US Department of Health and Human Services, Center for Drug Evaluation and Research. Guidance for industry. Chronic hepatitis C virus infection: developing direct-acting antiviral drugs for treatment. November 2017.

# SIMPLIFY STUDY: PWID Characteristics

Select Baseline Characteristics		N=103
Injection drug use	Any injection drug use in the past 6 months	100%
	Any injection drug use in the past 30 days	74%
	At least daily injection drug use in the past 30 days	26%
Non-injection drug use in the past 30 days		54%
History of MAT use		82%
Current MAT	Methadone	44%
	Buprenorphine	4%
	Buprenorphine-naloxone	12%
Alcohol use in the past 30 days		60%
Unstable housing <sup>a</sup>		23%

- <sup>a</sup>Stable housing was defined as a rented or privately owned house or apartment.
- Grebely J, et al. *Lancet Gastroenterol Hepatol*. 2018;3(3):153-161.

# SIMPLIFY STUDY RESULTS

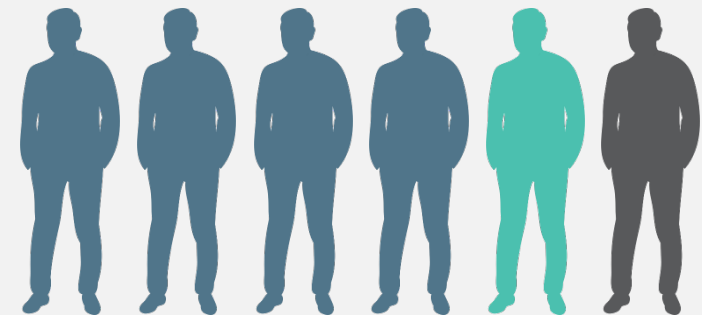
## SIMPLIFY ITT POPULATION<sup>1</sup>

**94%** **OVERALL  
CURE RATE**  
(n=97/103)

in GT 1-4 adult PWID patients with HCV, including those on MAT for opioid use disorder, without cirrhosis or with compensated cirrhosis<sup>1</sup>

SVR12 was the primary endpoint (HCV RNA <LLOQ 12 weeks after treatment completion).<sup>2</sup>  
Achieving SVR12 is considered a virologic cure<sup>3</sup>

■ Lost to follow-up ■ Overdose death ■ Reinfection



Among the 6 patients who did not achieve SVR12, 4 were lost to follow-up, 1 died of an overdose, and 1 was reinfected. There were **NO CASES OF VIROLOGIC FAILURE OR RELAPSE<sup>1</sup>**

ITT=intent-to-treat.

1. Grebely J, et al. *Lancet Gastroenterol Hepatol*. 2018;3(3):153-161. 2. EPCLUSA US full Prescribing Information. Gilead Sciences, Inc. Foster City, CA. April 2022. 3. US Department of Health and Human Services, Center for Drug Evaluation and Research. Guidance for industry. Chronic hepatitis C virus infection: developing direct-acting antiviral drugs for treatment. November 2017.

# Hepatitis C Treatment Among PWID: HERO Study

- ❑ Non-SVR associated with: stimulant use, reusing needles, injecting > 3x/d, sharing needles, cookers, rinse, and backloading drugs
- ❑ Incidence rate of reinfection 5.9 per 100-person years
- ❑ Higher rates among people with recent IDU or ongoing noninjection drug use (6.2 per 100 py)
- ❑ Lower among those receiving opioid agonist therapy (3.4 per 100 py)

**EDUCATION ABOUT AND ACCESS TO HARM REDUCTION IS KEY!!!**



# Take Home Message

HEPATITIS C SCREENING AND TREATMENT SAVES LIVES,  
PREVENTS NEW INFECTIONS, AND IS COST SAVING

## Addressing Challenges Remaining

- Increase awareness and universal screening across all THOs
  - Include CHA/Ps in rural clinics
- Increase capacity to treat – Educate more HCPs across the State
- Utilize telemedicine to treat those in remote communities
- Engage pharmacists and nurses across THOs to champion HCV treatment
- Meet hard to reach populations where they can be found
- Future: Embrace 1 stop Testing and Treatment

## Post-Talk Question

How many people does 1 untreated person with hepatitis C who injects drugs infect within first 3 years of initial infection?

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Thank you!

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