Hepatitis C: The *Challenges of and Opportunities for HCV Screening and Treatment of Alaska Native persons Living in Remote Communities in* 2020

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ALASKA NATIVE
TRIBAL HEALTH
CONSORTIUM

Conflict of Interest Disclosure Statement

* The LDHP has received two research grants from Gilead Sciences. None of my salary is funded by either of these grants

Goals for this Presentation

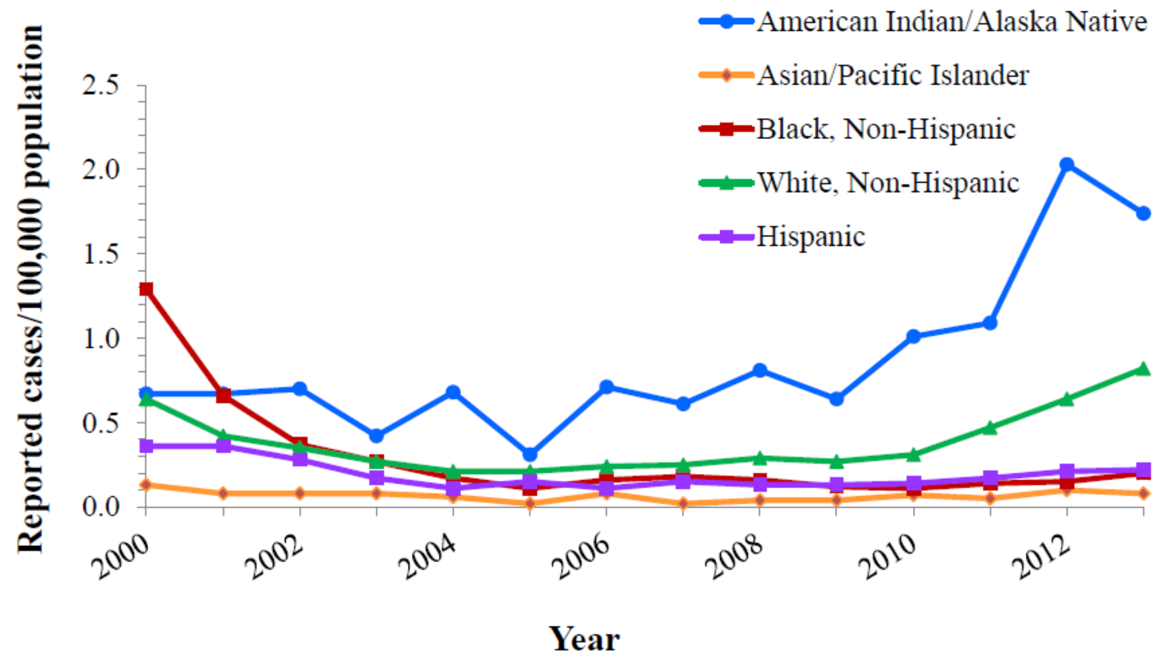
* Epidemiology of HCV in Alaska, especially in remote communities
* Understand who should be screened to detect chronic HCV infection based on recommendations from the CDC & USHSTF
* Understanding the barriers for persons with HCV living in rural communities to receive testing and treatment
* Understanding how this could be remedied with a "one stop shopping" approach for CHAP screening and treatment with Telemedicine support from the ANTHC Liver Program

The Two Epidemics of Hepatitis C in the USA and Alaska

* Epidemic in the 1960's, 1970's and Early 1980's
  * Related to IDU use, unscreened blood transfusions, unregulated tattooing and lack of universal precautions before HIV
    * 60%-70% due to IDU
    * 30%-40% due to lack of universal precautions
    * Up to 50% of those infected as baby boomers will likely have either cirrhosis or advanced fibrosis leading to liver failure and/or liver cancer in the next decade
* Current epidemic since 2010 from recent surge in injection opioid and other drug use that has been effecting many rural communities
  * Up to 60%-90% of IDU will acquire HCV infection within one year of starting

* Hepatitis C is the most common blood-borne pathogen in the U.S.
* More than 3 million Americans are living with HCV with 17,000 new cases identified each year.
* It is the leading cause of complications from chronic liver disease.
* Prior to COVID-19, it was associated with more deaths than the top 60 reportable infectious diseases in the US combined.
* Only 55.6% of adults diagnosed with HCV reported knowing they had hepatitis C.
* The highest rates of acute HCV are seen in American Indian/Alaska Native people.

Increases in Reported cases Acute Hepatitis C in U.S



2010 to 2013

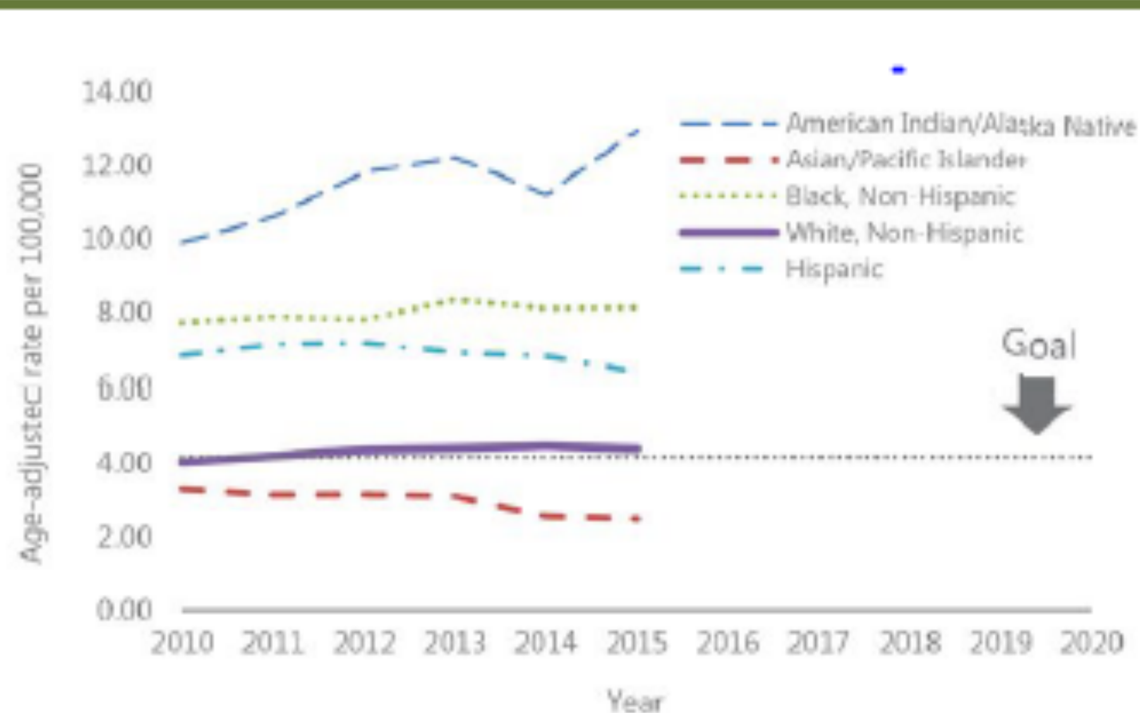
Overall 2.5X increase

2.7X increase amongst 20-29 year olds

2012 to 2013

86.2% increase among American Indian/Alaska Native persons

Age-adjusted rate* of HCV-related deaths,† by race/ethnicity¶



American Indians/Alaska Natives have the highest death rates of all racial/ethnic populations, and rates for this group increased by 16% from 2014 to 2015. Death rates are also elevated for non-Hispanic black and Hispanic persons compared with other populations.

Source: CDC, National Vital Statistics System†‡

*Rates for sex and race/ethnicity are age-adjusted per 100,000 U.S. standard population in 2000.

†Cause of death is defined as the underlying cause of death or one of the multiple causes of death and is based on the International Classification of Disease, 10th Revision (ICD-10) codes B17.1 and B18.2.

‡2 deaths in 2010, 1 death in 2011, 2 deaths in 2012, 2 deaths in 2013, 5 deaths in 2014, and 1 death in 2015 are not represented due to missing age data.

¶65 deaths in 2010, 73 deaths in 2011, 126 deaths in 2012, 111 deaths in 2013, 142 deaths in 2014, and 157 deaths in 2015 are not represented due to missing race/ethnicity data.

Deaths from Cancer, 1990-2015

Deaths from liver cancer
Increased 60%

Overall deaths from
cancer declined 26%

Source: CDC.gov

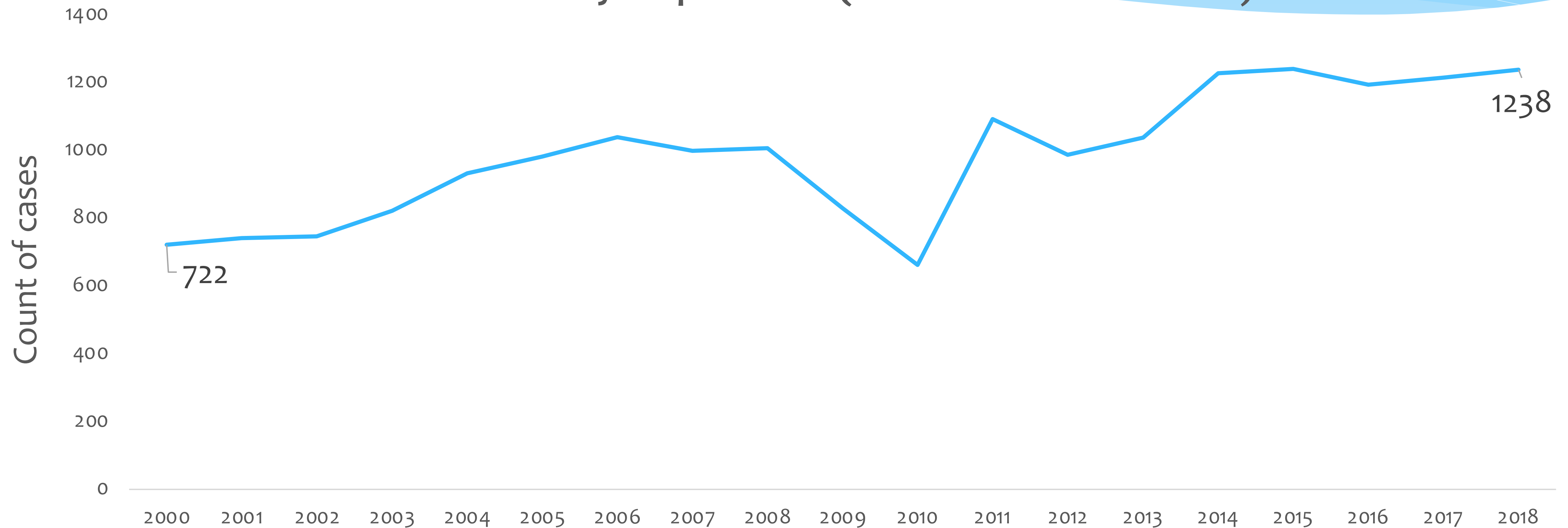
Estimate of HCV Infected Persons in State of Alaska

* Due to the opioid epidemic, the influx of persons with new HCV diagnosis far outstrips number of persons with HCV who have been treated and cured

Opioid Use in Alaska

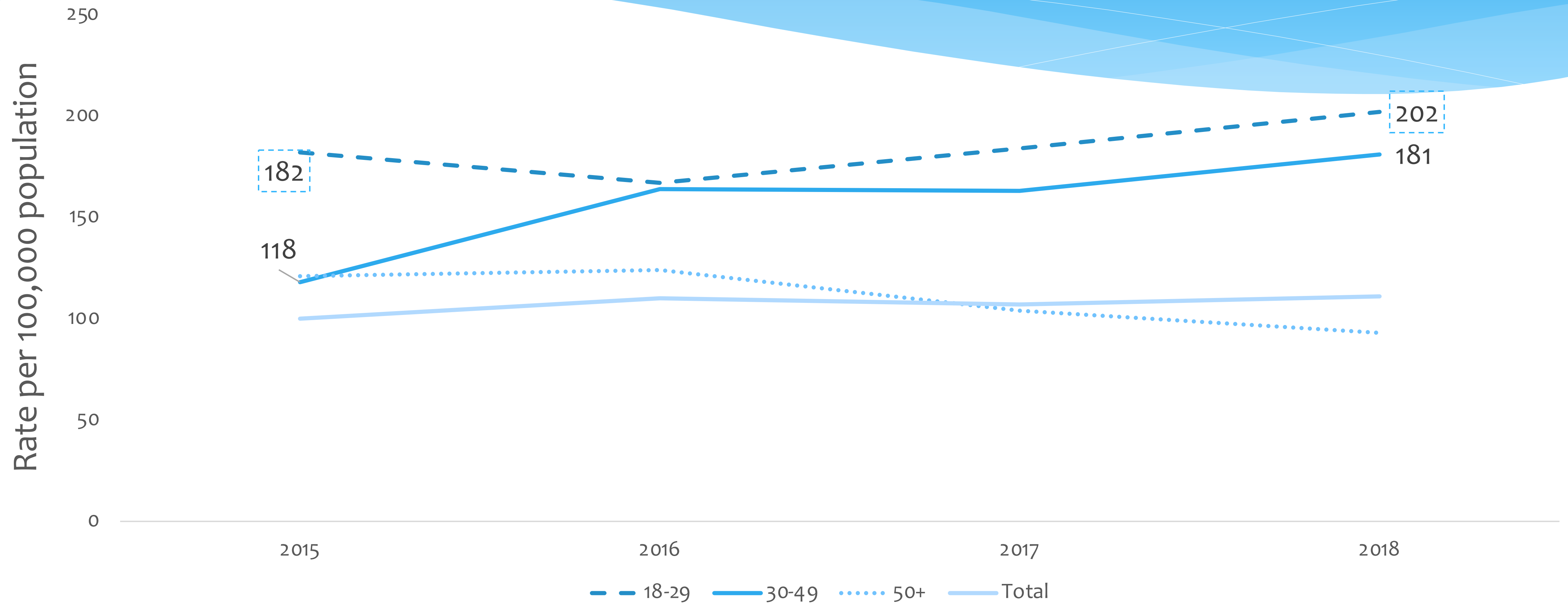
* Opioid overdose rates have increased in both Alaska Native and non-Native persons
  * Rates are consistently higher in Alaska Native than non-Native persons
  * Fentanyl overdose rates have increased since 2016
  * Opioid death rates have increased in Alaska Native persons and now exceed rates in non-Native persons
  * Needle exchange rates have tripled since 2013

Reported Hepatitis-C cases in Alaska, 2000-2018



SOURCE: Alaska Section of Epidemiology, Alaska Department of Health and Social Services (2019)

Alaska Hepatitis-C rate per 100,000 population by year and age group, 2015-2018



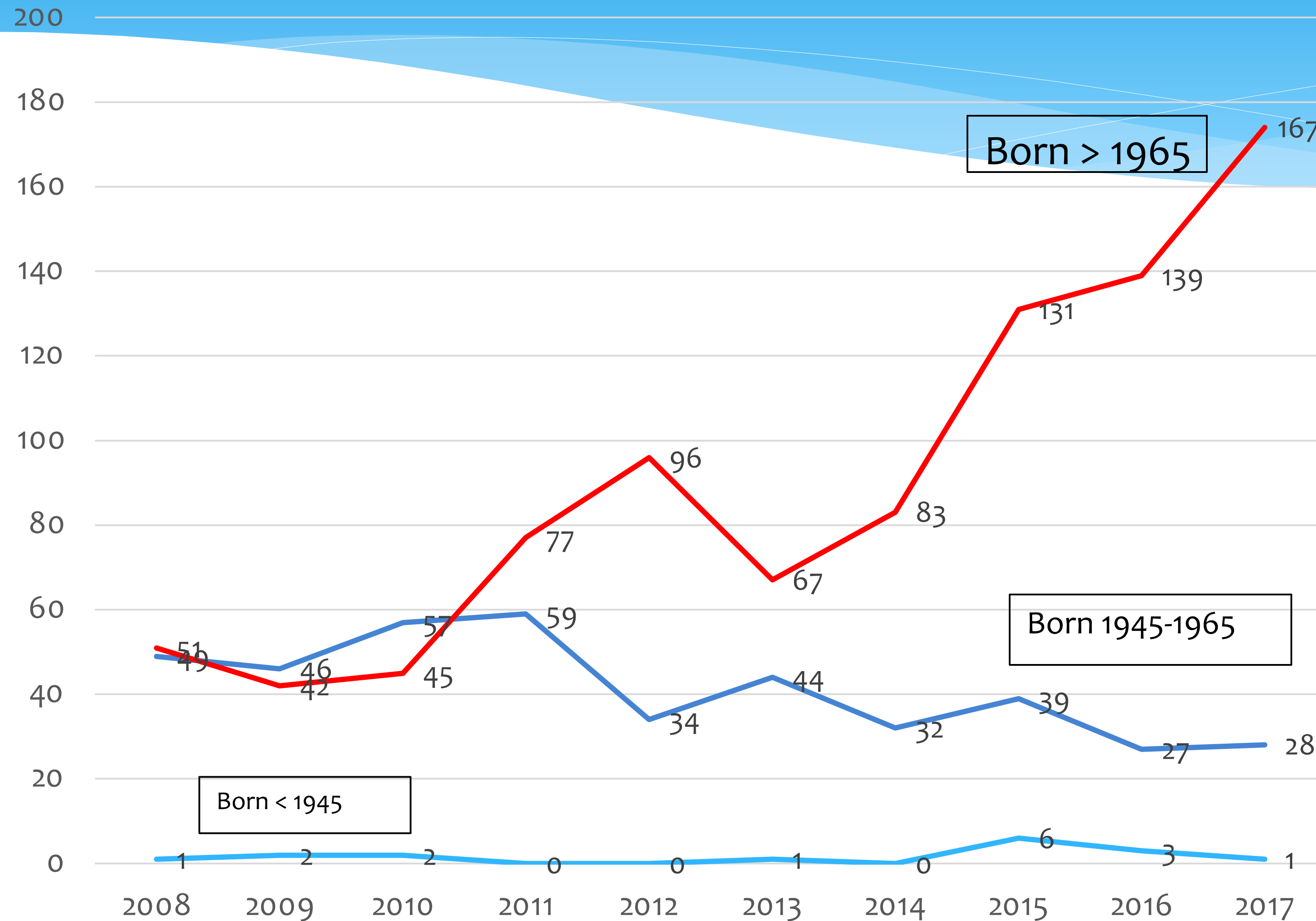
Source: Alaska Division of Public Health, Section of Epidemiology (2019)

Alaska HCV antibody screening and RNA testing, total tests conducted and proportion of positives, week #38, 2019 (September 15-21) and last 12-month period

HCV Antibody screening	Total Tested	Total Positive
Week #2019-38	78	17 (21.8%)
Last 12 month period	5,802	912 (15.7%)
HCV RNA testing		
Week #2019-38	16	11 (68.8%)
Last 12 month period	871	592 (68.0%)

SOURCE: Alaska Department of Health and Social Services, Division of Public Health, Laboratories

Hepatitis C On the Rise: Data from ANTHC



Where is Hepatitis C Found In Alaska?

Barriers to Get Screening and Treatment for those NA Living in Rural Communities

* We have over 180 persons in our database who live in remote communities who are HCV RNA-positive who have not yet been treated
* Currently to be treated these patients need to be able to travel at least 3-4 times from their community to the nearest regional or sub-regional facility with a provider who can assess them for treatment and prescribe antiviral medication
* Now a rapid finger stick screening test is available for anti-HCV that is CLIA waived, Oraquick made by Orasure Technologies

Proposal for CHAP for Screening for HCV in Rural Communities: One Stop Shopping

* OraSure OraQuick HCV Rapid Antibody Test
  * Finger stick whole blood
  * Results in 20 minutes max
  * CLIA waived
  * Cost $438.75 for a box of 25 tests, $17.50/test
  * If positive, CHAP would need to draw blood and send sera for HCV RNA
  * If HCV RNA is positive:
    * Regional provider would get approval for prior authorization from Medicaid or fill out paper work with patient for free drug program from Pharmaceutical Company
    * Telemedicine schedule of appointments would be arranged with ANTHC Liver Disease Program to co-treat with CHAP and the patient present
    * CHAP would draw f/o blood for HCV RNA 12 weeks after DAA therapy is completed

Quick Reference Guide

OraQuick® HCV Rapid Antibody Test

Step 1. Collect Sample

Fingerstick Whole Blood

Cleanse finger. Air dry.
Puncture with lancet.

Wipe away first drop of blood.
Fill the Collection Loop.

Venous Whole Blood

Validated for EDTA, sodium heparin, lithium heparin and sodium citrate

Collect blood using standard phlebotomy procedures.

- Whole blood may be stored at 2-8°C (36-46°F) for up to 7 days or 15-30°C (59-86°F) for up to 3 days.
- Invert the tube several times to mix.

Fill the Collection Loop.

Mix Sample

Immediately insert the Loop into the Developer Solution Mix.

Go to Step 2

Step 2. Perform the Test

Insert device into buffer.

Start the timer.

Pink fluid travels through the Result Window.

- DO NOT remove the device from the Developer Solution while the test is running.

2016/2017 National Academy of Science and Medicine Report

* Hepatitis C could now be easily cured with DAA
* Only a little more than half of baby boomer have been screened
* So far Federal, State and Local government governments have been unable to come up with sufficient recourses for HCV eradication

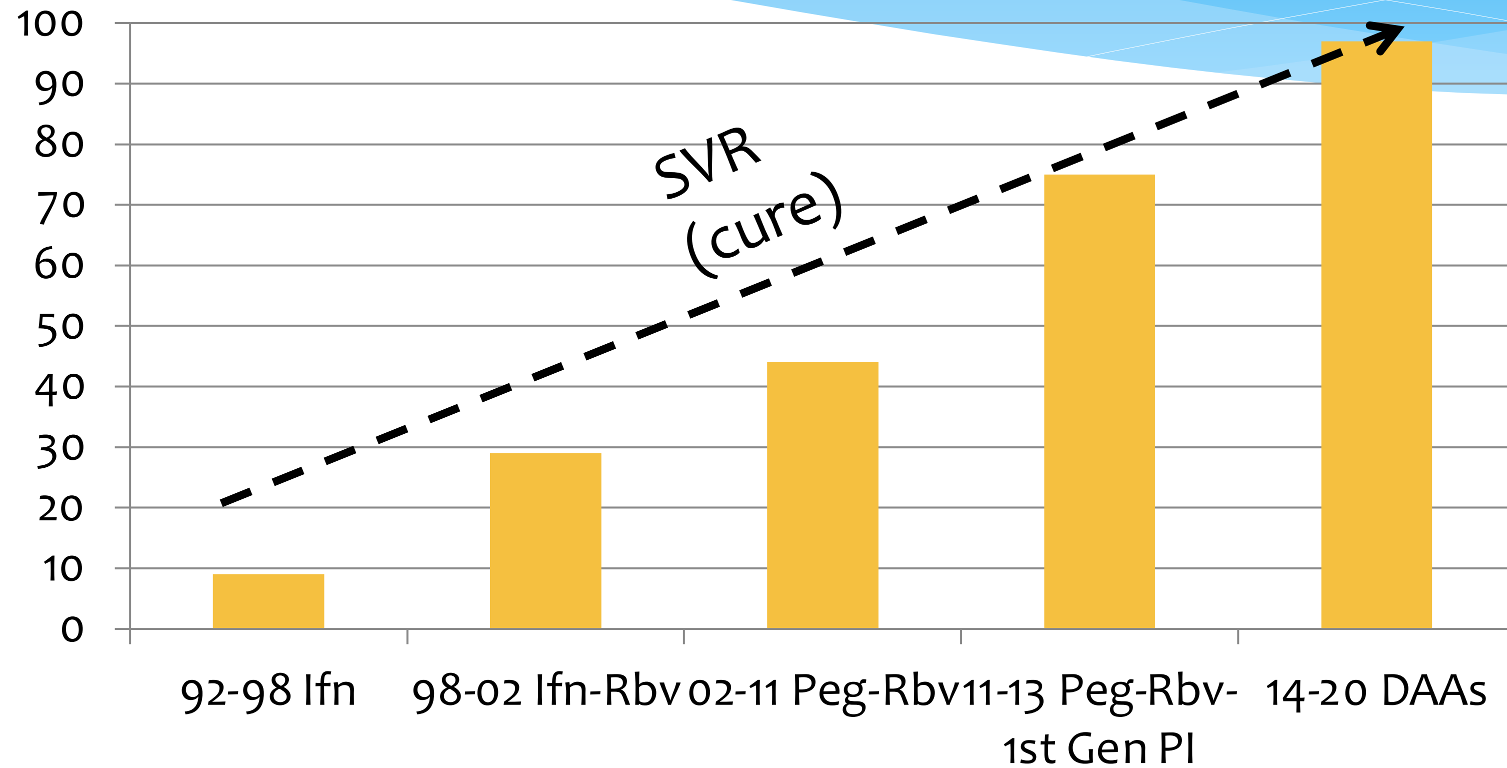
Assessing Fibrosis Stage in Persons with Chronic HCV: Why is this important

* Medicaid and most insurers in Alaska no longer require fibrosis staging
  * Persons still using drugs or alcohol can be treated
* Fibrosis remains important to identify those persons with advanced fibrosis or cirrhosis (F3-F4)
  * Appearance of HCC may occur in persons with a pre-existing malignancy in first 1-2 years
    * Highest risk in persons whose AFP does not fall to normal after SVR
  * In general, in persons cured of HCV by interferon therapy the future risk of HCC does decrease up to 75% over the following 5 to 10 years
  * Extent of reduction in rate of HCC has not been determined after DAA SVR
  * Persons with pre-existing advanced fibrosis or cirrhosis are still at risk and need regular surveillance with AFP and liver US every 6 months

How Can the Incidence and Prevalence of HCV in the US be Reduced in the Near Future? CDC, IHS, AASLD, IDSA and IOM Recommendations

- USHSTF/CDC now recommend universal screening all adults one time ages 18-79 : Insurers will cover
  - Baby boomers: ~50% can have advanced fibrosis/cirrhosis
- Other high risk groups: screen more frequently
  - IDU
  - Persons with a history of incarceration
  - All Pregnant women

HCV Treatment Revolution 2014-present



Every Person can be Treated at no or Minimal Cost to them or THO's

* Covered by Alaska Medicaid
* Medicare
* Private Insurances
* Require Prior Authorization before Prescription Dispensed
* Pharmaceutical Assistance Programs to Cover Those Uninsured or Who Cannot Afford Copayments

  www.abbvie.com/patients/assistance

  www.mysupportpath.com

Put These Drugs on Your Formulary as the are Revenue Generating

Tools for Prevention of SVR

* Needle Exchange
* Treatment of IDU as prevention

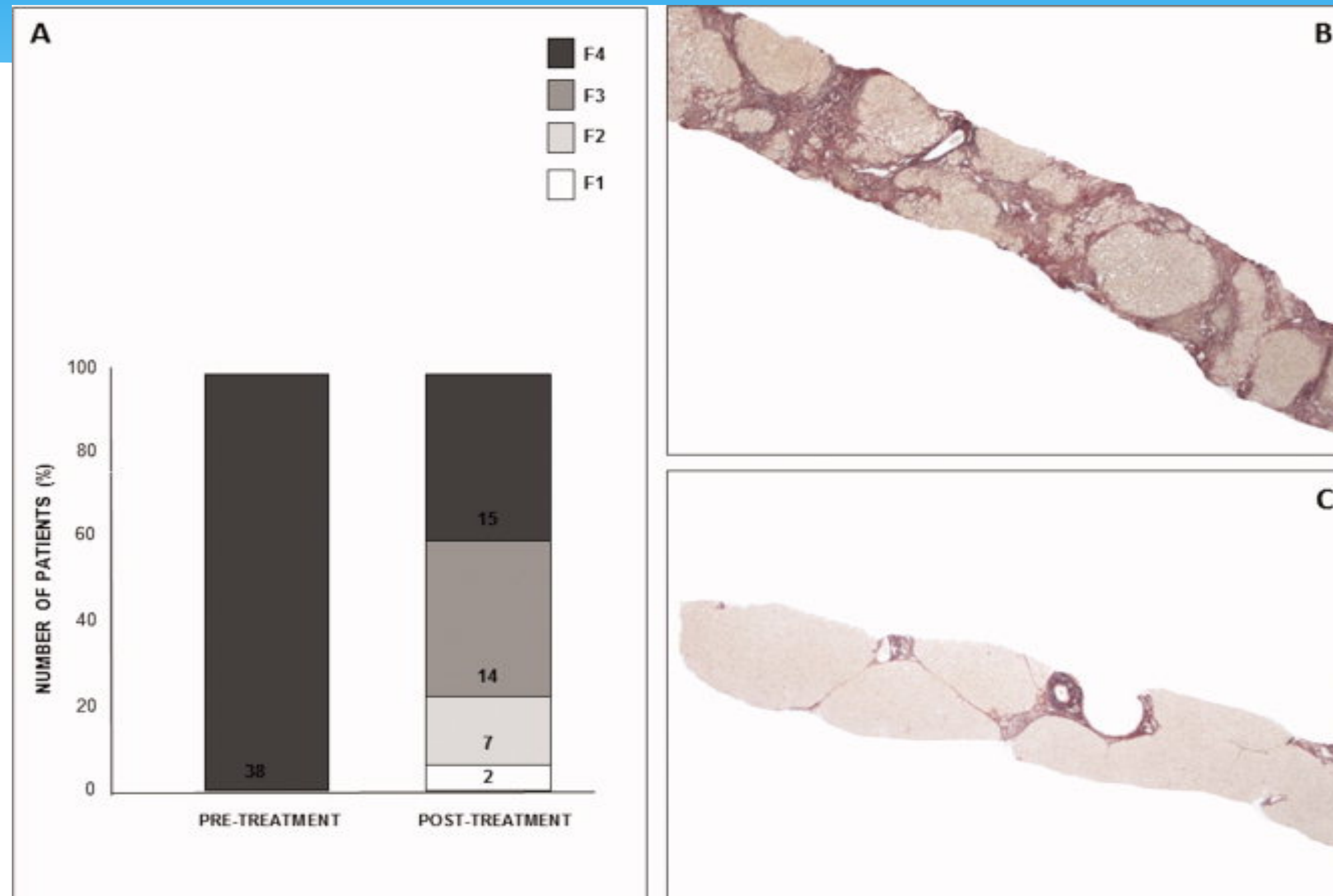
To Eliminate HCV We Must Screen and Treat Beyond the Traditional Venues

- Treatment of infected persons: PCP on the frontline
  - Screening and Treating persons in rural Alaskan Communities
    - CHAP screening all adults once and high risk persons yearly with rapid finger-stick test and treatment of those HCV RNA+ via telemedicine (one stop shopping in the communities)
  - Screening and Treating incarcerated persons: now done in Alaska
  - Treating persons in drug rehab programs, programs serving homeless persons, needle exchange programs, safe injecting and other non-traditional sites
  - Treatment as prevention
- No Vaccine on horizon for decade or more

Good News: Early Cirrhosis Can be Completely Reversed!

* Remove the cause of cirrhosis and reversal will take place over about 10 years
  * HBV: Antiviral medication (tenofovir)
  * HCV: Treat and cure
  * Alcohol: Stop drinking alcohol
* Even 30% to 50% of persons with decompensated cirrhosis will become compensated (look normal clinically and by LFT) after proper treatment

A morphometric and immunohistochemical study to assess the benefit of a sustained virological response in hepatitis C virus patients with cirrhosis



Hepatology
Volume 56, Issue 2, pages 532-543, 2 JUL 2012 DOI: 10.1002/hep.25606
http://onlinelibrary.wiley.com/doi/10.1002/hep.25606/full#fig1

Program for the elimination of HCV

* Right now a “pipe dream” but actively pursued by the Hepatitis Alaska Working Group (HAWG)
* Must consist of community wide participation to achieve any measure of success
* Must include: Screening and Linkage to Care of:
  * Baby Boomers and all adults
  * Drug treatment programs, homeless persons, needle exchange programs
  * Screening for hepatitis B and C in Prisons
    * Vaccination for those negative for HBV
    * Treatment for those positive for HCV
  * Pregnant females: Alaska Native Medical Center (ANMC) in Anchorage
  * Emergency Departments

HAWG Collaboration with Many Partners in Alaska

* All Alaska Native Tribal Health Organizations
* CDC; Arctic Investigations Program and Division of Viral Hepatitis
* State of Alaska Depts. of Epidemiology, Public Health Nursing and HIV
* Municipality of Anchorage
* Anchorage Community Health Center
* Anchorage Needle Exchange Program
* Alaska State Prisons
* University of Alaska, Anchorage
* University of Washington, Seattle
* WWAMI Alaska Medical School
* Private Sector
* The Hepatitis Alaska Working Group (HAWG)
  * Meets Quarterly to discuss collaboration on viral hepatitis

HAWG Accomplishments to date

* Developed a curriculum to train primary care providers to diagnose, estimate the level of liver fibrosis and treat HCV, obtain funding for DAA for their patients and continual follow-up of patients after SVR who have F3-F4 fibrosis
  * Have put on five half day training programs for providers around the state with CME and documentation that they are now trained to treat HCV without a consult
* Continuing to update the ANTHC website www.anthc.org/hep for both patients and providers contains information, treatment algorithms and treatment forms for printout
* Participant in three project ECHOs, Alaska, NW Indian and IHS
* Conduct a monthly telemedicine accredited CME statewide and beyond for health personal

ANTHC Liver Disease & Hepatitis Program

Visit our website:
www.anthc.org/hep

LiverConnect
2nd Tuesdays,
8-9am AK time
CEUs provided

ALASKA NATIVE TRIBAL HEALTH CONSORTIUM
Who We Are | What We Do | Working with Us | Contact Us

FIND OUT IF YOU HAVE HEPATITIS
IT COULD SAVE YOUR LIFE

Liver Disease & Hepatitis Program

Our mission is to conduct activities that will serve to improve the health of Alaska Native and American Indian persons who either have or are at risk of getting viral hepatitis or other liver diseases

About Our Program

for Patients
Hepatitis is a disease

for Providers
Providing support to patients

Hepatitis C Treatment

Conclusions

* Chronic HCV is a progressive disease that leads to cirrhosis over 20-40 years in at least half of infected persons
* Cure of HCV reduces the risk of liver complications in those with advanced liver disease and likely eliminates development of cirrhosis or HCC in those with mild to moderate liver fibrosis
* Enhanced screening for infected persons and universal treatment can greatly impact the future development of liver related death and costs
* Currently, persons living in remote communities have large barriers to obtain screening and treatment for HCV
* ANTHC Liver Program is seeking financial support for a pilot village screening and treatment program