

Alaska ID ECHO: HCV-HIV-PrEP-STIs



March 8, 2022

The ANTHC Liver Disease and Hepatitis Program, HIV Clinical Services, Behavioral Health Department and Southcentral Foundation's Pharmacists have partnered to host this ECHO, and it's funded by a grant from the Northwest Portland Area Indian Health Board.

Welcome to Alaska Infectious Disease ECHO – HCV, HIV, PrEP, STIs

Approved Provider Statements:



In support of improving patient care, Alaska Native Medical Center (ANMC) is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

Contact Hours:

ANMC designates this activity for a maximum of 12 contact hours, including 3 total pharmacotherapeutics contact hours, commensurate with participation.

Financial Disclosures:

Youssef Barbour, MD & Lisa Townshend-Bulson, APRN / faculty for this educational event, are primary investigators in an ANTHC sponsored hepatitis C study funded in part by Gilead Sciences. All of the relevant financial relationships listed have been mitigated.

Requirements for Successful Completion:

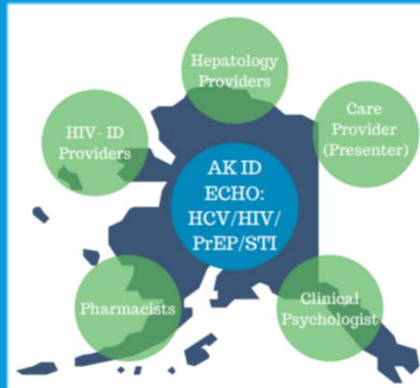
To receive CE credit please make sure you have actively engaged in the entire activity, your attendance is recorded by the facilitator, and complete the course evaluation form found here: <https://forms.gle/1Bt4EqvN2WdnM4P77>



For more information contact
jfielder@anthc.org or (907) 729-1387



AK ID ECHO: CONSULTANT TEAM



- Youssef Barbour, MD Hepatologist
- Leah Besh, PA-C HIV/Hepatology Provider
- Terri Bramel, PA-C HIV/STI Provider
- Rod Gordon, R.Ph. AAHVP Pharmacist
- Jacob Gray, MD Infectious Disease Provider
- Annette Hewitt, ANP Hepatology Provider
- Brian McMahon, MD Hepatologist
- Lisa Rea, RN HIV/STI Case Manager
- Lisa Townshend, ANP Hepatology Provider



Simplified Hepatitis C Treatment

Lisa Townshend-Bulson, FNP-C

Annette Hewitt, FNP-C

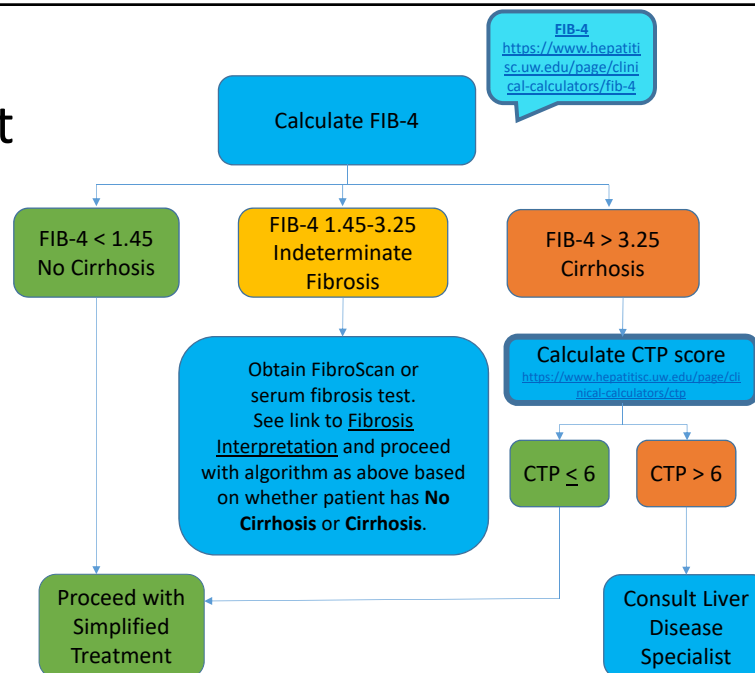
ANTHC Liver Disease & Hepatitis Program

Changing Mindset About Hepatitis C

- Remove the barriers
- See hepatitis C as an infection that needs to be treated
- Recognize that hepatitis C treatment is affordable



Simplified Treatment



Who Is Eligible for Simplified Treatment*

Adults with hepatitis C (any genotype) who do NOT have cirrhosis or have compensated cirrhosis (CTP score ≤ 6) and persons who have not previously received HCV treatment

*ANTHC Simplified Treatment has been adapted from AASLD/IDSA HCV Guidelines available at:
www.hcvguidelines.org/

Who Is *NOT* Eligible for Simplified Treatment

Patients who have any of the following:

- Prior HCV treatment
- Current or prior episode of decompensated cirrhosis, defined as Child-Turcotte-Pugh (CTP) score > 6 or presence of ascites, hepatic encephalopathy, total bilirubin $> 2.0\text{mg/dL}$, albumin $\leq 3.5\text{g/dL}$, or INR ≥ 1.7
- HIV positive
- HBsAg positive
- Current pregnancy
- End-stage renal disease (i.e. eGFR $< 30\text{mL/min/m}^2$)
- Known or suspected hepatocellular carcinoma
- Prior liver transplantation

Simplified Treatment – 3 Easy Steps

- 1 Determine FIB-4 score (need age, ALT and AST, and platelet count)
- 2 Get labs
- 3 Write Prescription

Simplified Treatment – 3 Easy Steps

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Simplified Treatment – 3 Easy Steps

Step 1

Determine FIB-4 score

Fibrosis-4 (FIB-4) Calculator

[Share](#)

The Fibrosis-4 score helps to estimate the amount of scarring in the liver. Enter the required values to calculate the FIB-4 value. It will appear in the oval on the far right (highlighted in yellow).

$$\text{FIB-4} = \frac{\text{Age (years)} \times \text{AST Level (U/L)}}{\text{Platelet Count (10}^9\text{/L)} \times \sqrt{\text{ALT (U/L)}}} = \text{[Yellow Oval]}$$

Interpretation:

Using a lower cutoff value of 1.45, a FIB-4 score <1.45 had a negative predictive value of 90% for advanced fibrosis (Ishak fibrosis score 4-6 which includes early bridging fibrosis to cirrhosis). In contrast, a FIB-4 >3.25 would have a 97% specificity and a positive predictive value of 65% for advanced fibrosis. In the patient cohort in which this formula was first validated, at least 70% patients had values <1.45 or >3.25. Authors argued that these individuals could potentially have avoided liver biopsy with an overall accuracy of 86%.

<https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4>

FIB-4 Interpretation

FIB-4 < 1.45
No Cirrhosis

FIB-4 1.45-3.25
Indeterminate
Fibrosis

FIB-4 > 3.25
Cirrhosis

What to do if score is indeterminate or indicates cirrhosis

FIB-4 1.45-3.25
Indeterminate
Fibrosis

FIB-4 > 3.25
Cirrhosis

Obtain FibroScan or
serum fibrosis test.
See link to [Fibrosis Interpretation](#)
and proceed with algorithm as
above based on whether patient
has **No Cirrhosis** or **Cirrhosis**.

Calculate
CTP score

Simplified Treatment – 3 Easy Steps

Step 2 Get labs

Step 2. Obtain Pre-Treatment Labs

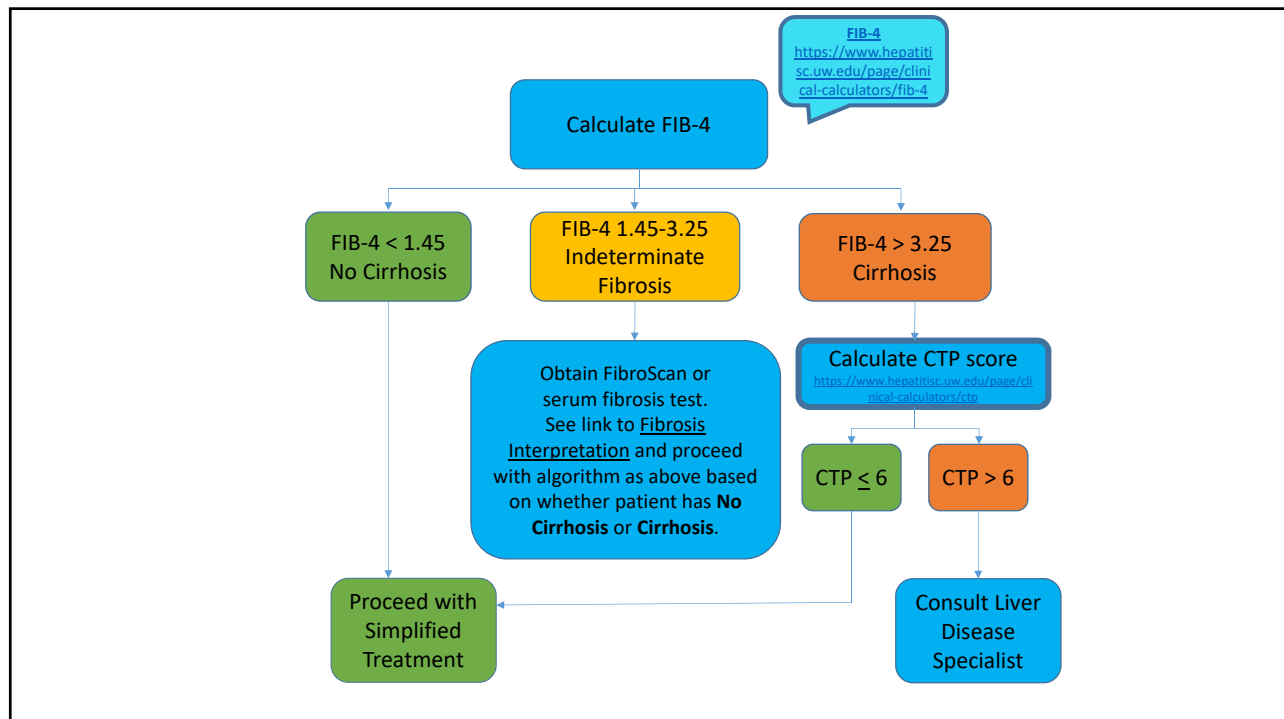
Lab	When Needed?
Serum Fibrosis Test (FibroSure/Labcorp or FibroTest/Quest) if FIB-4 is indeterminate (1.45 – 3.25) or obtain FibroScan if test available (i.e. ANMC)	Complete prior to choosing HCV medication
Pregnancy Test	Immediately prior to treatment start and counsel about pregnancy risk with HCV medication
HCV RNA	Acceptable within past 6 months
Hepatic function panel and eGFR	Acceptable within past 6 months
AFP	Acceptable within past 6 months
CBC (without diff)	Acceptable within 3 months if cirrhosis, 6 months if no cirrhosis
HIV antigen/antibody	Anytime prior
Hepatitis B surface antigen	Anytime prior
CMP and PT/INR (only needed in cirrhosis)	Acceptable within 3 months
HCV genotype (only needed if patient has cirrhosis and you are treating with sofosbuvir/velpatasvir)	Anytime prior

Fibrosis Interpretation

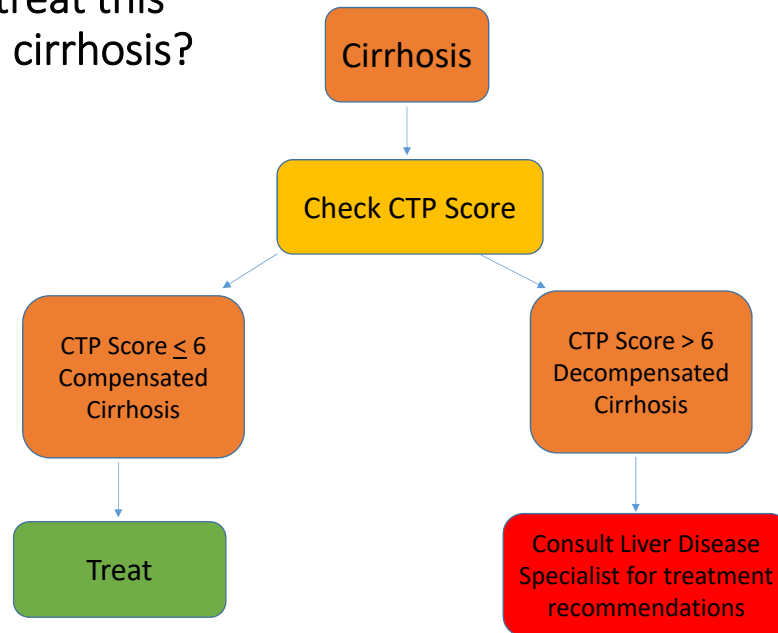
For serum fibrosis tests such as FibroSure (Labcorp) or FibroTest (Quest), use the following cutoffs:			FibroScan			
F0-F2	F3*	F4*	F0-F1	F2	F3	F4
< 0.48	0.48-0.74	> 0.74	< 8.4	8.4 – 9.5	9.6 – 12.7	≥ 12.8

F0-F3 = Treat as No cirrhosis F4 = Cirrhosis

*Those with scores indicating F3-F4 fibrosis prior to treatment (highlighted in yellow) should undergo surveillance for hepatocellular carcinoma with **RUQ US and AFP every 6 months**. Consult Liver Disease Specialist with any questions.



Should you treat this patient with cirrhosis?



Simplified Treatment – 3 Easy Steps

Step 3

Write Prescription

Appropriate Treatment Regimens

No Cirrhosis

Options

Glecaprevir/Pibrentasvir
(Mavyret™)
3 tablets daily
for 8 weeks

Sofosbuvir/Velpatasvir
(Epclusa®)
1 tablet daily
for 12 weeks

Appropriate Treatment Regimens

Compensated
Cirrhosis

Options

Glecaprevir/Pibrentasvir
(Mavyret™)
3 tablets daily
for 8 weeks

Sofosbuvir/Velpatasvir
(Epclusa®) ¹
1 tablet daily
for 12 weeks

¹ Obtain genotype if treating with Epclusa. If genotype 3, obtain NS5A RAS testing and if Y93H RAS is negative, proceed with Epclusa treatment. If Y93H RAS is present, refer to Liver Disease Specialist.

When writing prescription, identify insurer and determine if prior authorization needed

Medicaid

- Glecaprevir/Pibrentasvir – is preferred medication/No prior authorization.
- All other regimens, including Sofosbuvir/Velpatasvir require prior authorization

Medicare Part D – Prescription Drug Coverage

- Determine plan and identify HCV treatment on formulary
- At this time, plans require PA

Private Insurance

- Identify HCV treatment on formulary
- Obtain PA

Prescription Assistance for Uninsured or Underinsured

Non-pharmaceutical Sponsored Program

Pan Foundation

- Call 1-866-316-7263 or online www.panfoundation.org/hepatitis

Pharmaceutical Sponsored Patient Assistance Programs

myAbbvie Assist (Mavyret)

- Call 1-877-628-9738 or online www.abbvie.com

Gilead Support Path (Harvoni, Epclusa)

- Call 1-855-769-7284 or online www.mysupportpath.com

Pre-Treatment Checklist

- Determine hepatitis A vaccine status (if unknown, draw HAV antibody total IgG) and vaccinate if not immune
- Determine hepatitis B vaccine status (if unknown, draw HBsAg and HBsAb) and vaccinate if patient has not already completed hepatitis B vaccine series and HBsAg and HBsAb are negative)
- Review drug-drug interactions www.hep-druginteractions.org
- Assess mental health status (including depression using tool such as **PHQ-9**) and screen for active substance use disorder (SUD) and refer appropriately to Behavioral Health/treatment.
- Assess for Alcohol Use Disorder. Have patient complete **AUDIT-C**. Counsel if excess alcohol use, and refer for treatment as appropriate.
- Assess for ongoing injection drug use and connect patient with syringe service program (in Alaska: www.alaskanids.org, www.interioraids.org, or www.iknowmine.org for harm reduction/prevent reinfection
- Counsel patient about pregnancy prevention (Ethinyl estradiol not recommended with glecaprevir/pibrentasvir (Mavyret®)
- Review medication-specific information with patient at treatment start

Monitoring During Treatment

- No specific lab monitoring required but can be considered if clinically indicated.
- In-person or telehealth/phone visit may be scheduled for patient support, assessment of symptoms, and/or new medications
- Instruct patients taking diabetes medications to monitor for hypoglycemia
- Inform patients taking warfarin of potential changes in their anticoagulation status. Monitor INR for subtherapeutic anticoagulation is recommended.
- Refer to Liver Disease Specialist, any patient with worsening liver blood tests (e.g. bilirubin, AST, ALT); jaundice, ascites, or encephalopathy; or new liver-related symptoms.

Assessment of Cure (SVR) Very Important!!!

- HCV RNA and LFT 12 weeks or later after completing HCV medication
- If ALT/AST are elevated after SVR, assess for other causes of liver disease, see Elevated LFTs Algorithm

Follow-Up After Achieving Cure

- No liver specific follow-up necessary for patients with no-moderate fibrosis (F0-F2) who have achieved cure.
- For patients with advanced fibrosis/cirrhosis (F3/4 fibrosis), RUQ US and AFP is recommended every 6 months to screen for hepatocellular carcinoma.
- Yearly labs to assess for liver disease progression: CBC, LFTs (and AFP) for those with advanced fibrosis; CBC, CMP, PT/INR (and AFP) for those with cirrhosis.
- Counsel persons with risk for HCV infection (ongoing IVDU, MSM involved in condomless sex) about risk reduction and obtain HCV RNA yearly and whenever ALT, AST, or bilirubin are elevated to test for reinfection
- Counsel patients to avoid excess alcohol use. For those with cirrhosis, counsel abstinence from alcohol use.

Follow-Up for Patients Who Do Not Achieve a Cure

- Refer patient to Hepatology or other specialist for evaluation for re-treatment
- If unable to retreat, assess for liver disease progression every 6-12 months with LFT, CBC and INR
- For those with active hepatitis C, abstinence from alcohol is recommended.

Thank You!

Lisa Townshend-Bulson, MSN, APRN, FNP-C
ANTHC Liver Disease and Hepatitis Program
P: [907-729-1573](tel:907-729-1573)
ltownshend@anthc.org

Visit our website: www.anthc.org/hep
For helpful information and additional information about our other CE programs:
LiverConnect (CE program on liver disease – 2nd Tuesdays, 8-9am) and
AK Liver Disease ECHO (3rd Thursdays, 12n-1pm)



Case #1

Katy is a 22 year old female, diagnosed at age 18 with HCV, GT 2a. She has a history of IVDU. She just returned from treatment (not using drugs and alcohol for 4 months), working in landscaping and is living with an older sibling. She has no health care coverage. She made today's appointment to discuss hepatitis C treatment.

Chart review shows she's fully vaccinated against Hepatitis A and B. Hep B surface antigen negative.

Medications: ethinyl estradiol/norethindrone OCP, St. John's Wort

You get pretreatment labs...

Pre treatment Lab Review

HCV RNA - 1,003,458 iu/ml

CBC- WNL, Plt 340

ALT - 49, AST 34, Alk 69, Alb 4.6, t. bili 0.4

eGFR - 112

HIV – negative

HBsAg - negative

FIB-4: 0.31 (no or mild fibrosis)

What are her treatment options ?

Simplified Treatment

- Apply for Medicaid and if not eligible apply to patient assistance program for free medication
- Mavyret 3 tabs daily for 8 weeks
 - no prior authorization needed if Medicaid
 - switch to a different birth control – barrier or progesterone only contraception is ok
- Epclusa 1 tablet daily for 12 weeks
 - prior authorization required if Medicaid
- Assist with harm reduction, post treatment support program
- 12 weeks or more after treatment obtain HCV RNA and LFTs to test for cure

Patient Case AK-ID-14

Date	HCV RNA	ALT/AST
2/4/2022	9433	
2/16/2022		242/106
8/31/2021	2,217,218	
4/27/2021	undetectable	Over 4-5 months patient took a total of 2 weeks of Mavyret, starting around June 2020
12/4/2019	58,7001	
7/23/2018	107,148	
2/15/2018	+Ab, undetected RNA	

2/16/2022

WBC	6.94	T. Bilirubin	0.210.8	nonreactive HIV 11/10/2021
HGB	12.7	Total Protein	6.7	AFP
HCT	38	Albumin	4.0	Fe**
Platelets	328	A1c		TIBC**
PT/INR		Hep A Total Ab	nonreactive 1/21/2022	Ferritin**
GFR	120	HBsAg (pos/neg)*		ANA**
Creatinine	0.8	HBsAb (pos/neg)		AMA**
ALT	242	HBcAb (pos/neg)*	nonreactive 1/21/2022	IgG**
AST	106	HCV Genotype	1a	HBV Viral Load **
ALP	102	HCV Viral Load	9433 2/4/2022	HBV eAg/eAb* *

Question

Should treatment be re-initiated with Mavyret or with something else? Does he need another fibroscan?

Case #2

Paul is a 59 year old male found to be HCV antibody reactive on screening labs done during a physical. He was notified of results and returned for confirmatory testing:

HCV RNA was 8,987,654 iu/mL. (confirming active infection)

He returns to clinic today to review the results and wants to begin HCV treatment. He has AK Medicaid coverage

You review his most recent labs and consult the simplified treatment algorithm.

No history of hepatitis A or B vaccinations.

Medications – Lisinopril 10mg daily, atorvastatin 20mg daily

Lab Results

HCV RNA (viral count): 8,987,654 iu/mL. (confirms active infection)

CBC: Hgb 13.2, plt 160

CMP: ALT 68, AST 75, bili 0.9, alk phos 110, albumin 3.9, eGFR >60

HIV screen: negative

HBsAg: negative, HBsAb: neg, HBcAb: neg

HAV Total antibody: negative

FIB-4: 3.35 (cirrhosis)

Does he need additional tests?

- RUQ US (and AFP) now and every 6 months for life
- PT/INR - 1.1 (within 3 months)
- CTP score - 5 (Class A/compensated)
 - Use online calculator
 - Refer to hepatology if >6
- Genotype?
 - Not needed with glecaprevir/pibrentasvir (Mavyret)
 - Sofosbuvir/velpatasvir (Epclusa) – If genotype 3 will need to get NS3 lab, if Y93 positive refer to hepatology for treatment (ribavirin will be needed)

Simplified Treatment – Compensated Cirrhosis (CPT \leq 6)

- Mavyret 3 tabs daily for 8 weeks
 - no prior authorization needed
 - hold atorvastatin during treatment or switch to a different statin (rosuvastatin)
- Epclusa 1 tablet daily for 12 weeks
 - prior authorization required
 - If GT 3 and Y93 positive – refer to hepatology for treatment
- Vaccinate against hepatitis A and B – do not delay treatment start for vaccines
- 12 weeks or more after treatment obtain HCV RNA and LFTs to test for cure

ADDITIONAL LEARNING OPPORTUNITIES

ANTHC Liver Disease ECHO

- Third Thursday of every month from 12:00-1:00 PM AKST
- March 17: Diabetes Drugs that Help NAFLD

anthc.org/project-echo/alaska-liver-disease-echo

ANTHC LiverConnect

- Second Tuesday of every month 8:00-9:00 AM AKST
- April 12: Hepatitis C: Changing Demographics/Simplified Tx/Strategies for Tx and Prevention

anthc.org/what-we-do/clinical-and-research-services/hep/liverconnect



ADDITIONAL LEARNING OPPORTUNITIES

Addiction Medicine ECHO

- Second and fourth Thursday of every month from 12:00-1:00 PM

anthc.org/project-echo/addiction-medicine-echo

Indian Country ECHO Programs

- Harm Reduction, Infectious Disease, and more!

www.indiancountryecho.org/teleecho-programs



AK ID ECHO Contacts

ANTHC Staff

- Leah Besh PA-C, Program Director: labesh@anthc.org
- Jennifer Williamson, Program Coordinator:
907-729-4596 or jjwilliamson@anthc.org
- Lisa Rea RN, Case Manager: ldrea@anthc.org



ANTHC Liver Disease and Hepatitis Program: 907-729-1560

ANTHC Early Intervention Services/HIV Program: 907-729-2907

Northwest Portland Area Indian Health Board

- David Stephens: Director Indian Country ECHO: dstephens@npaihb.org
- Jessica Leston: Clinical Programs Director: jleston@npaihb.org



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TRIBAL HEALTH
CONSORTIUM



NPAIHB
Indian Leadership for Indian Health

Thank you!

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