

Addressing Transient Elastography (FibroScan): Integrating with HCV Care

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Describe Hepatitis C Elimination Program

Introduce Fibroscan Technology

Elimination

Reduction to zero of the incidence of disease or infection in a defined geographical area.

World Health Organization

80% of New HCV Infections Occur in People Who Inject Drugs (PWID)

HCV Program Design Considerations

PWID May Not Fit the Usual Healthcare Delivery Model We Created

Scheduled Office Visits

Follow Up with Testing and Imaging and Future Appointments

Convenient Contact with Telephone or Mail

Reliable Transportation

Ability to Safely Store Medication

Predictable Changes to Home Life: Hospitalization, Incarceration,

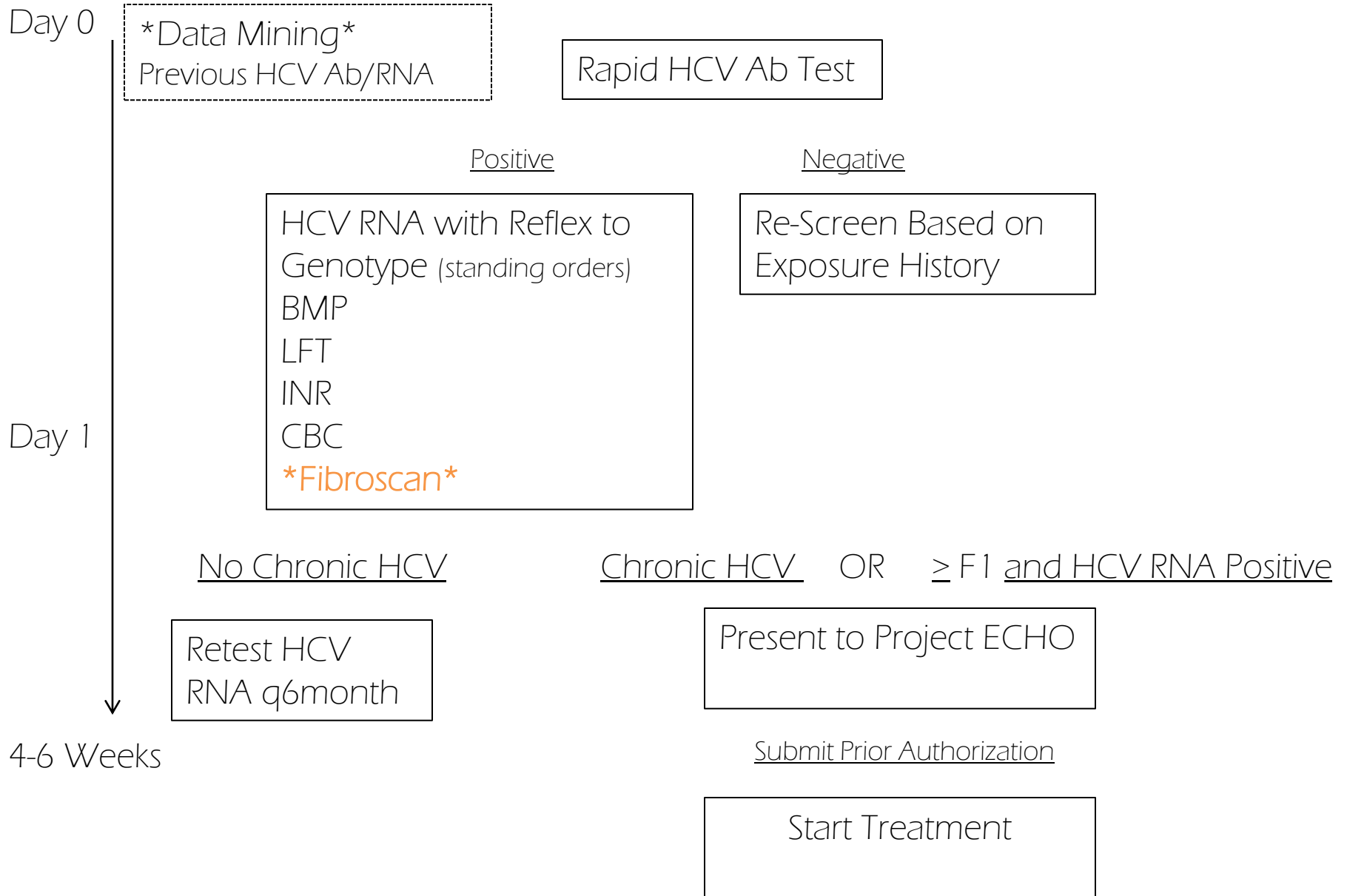
Drug/Alcohol Rehab

Family and Friend Support

We Had to Create A New Model of Healthcare Delivery

Initially, required multiple visits, could not get outside imaging, significant amount of human resources.

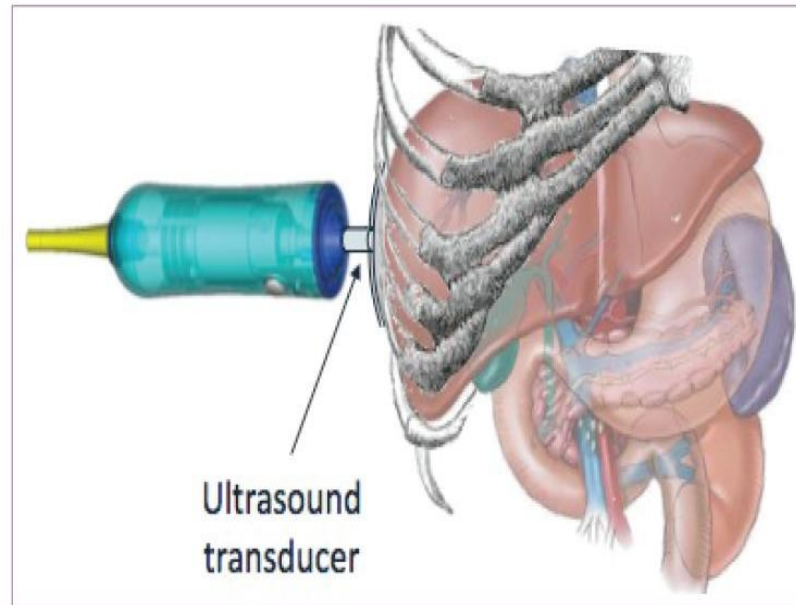
Single Visit Ready to Treat Program



Fibroscan: calculates liver stiffness based on sound wave.

Non-invasive. 10-15 Minutes.

RN, Rad Tech, MD



FibroScan Technology

Dual Function Liver Testing

- Transient Elastography (VCTE)
 - Surrogate marker of fibrosis
- Ultrasound attenuation rate (CAP)
 - Surrogate marker of steatosis



Mechanical Shear Wave Induction



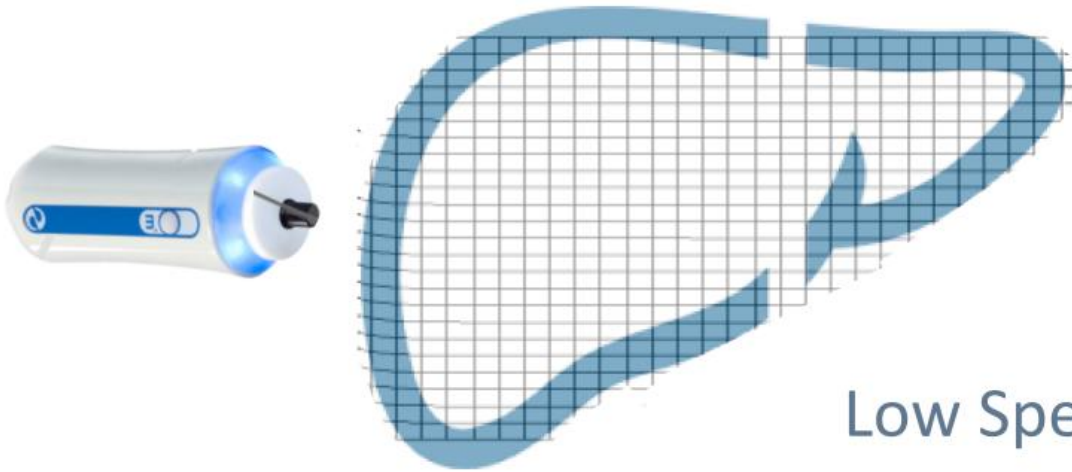
VCTE Measurement Steps

- Mechanically induce a shear wave
- Measure shear wave speed
- Calculate stiffness

FibroScan[®]

Shear Wave Speed Correlates to Stiffness

Hooke's Law

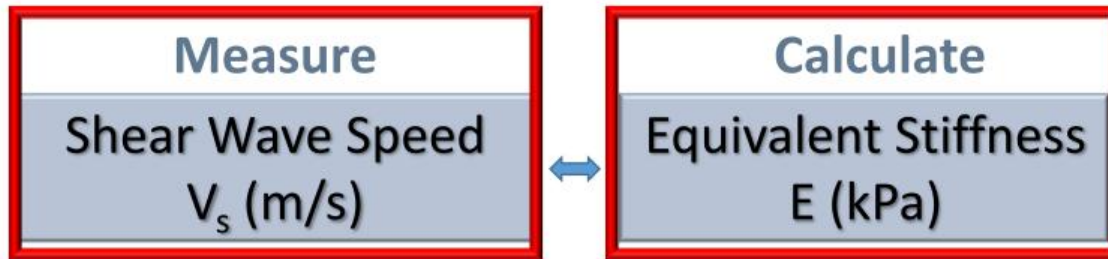


Low Speed = Low Stiffness

High Speed = High Stiffness

Stiffness Calculation Formula

Young's Modulus



$$E = 3\rho V_s^2$$

Elasticity
(Stiffness)

Liver Tissue
Density

Velocity of
Shear Wave

Peer Review Publications

- 1500 + peer review publications
- First line test in clinical practice guidelines



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Clinical Practice Guidelines

Guideline	Disease Etiology	Reference Citation
AASLD/IDSA	HCV	Recommendations for Testing, Managing and Treating Hepatitis C; When & In Whom to Initiate Antiviral Therapy, AASLD & IDSA Practice Guidelines; www.hcvguidelines.org
EASL	HCV	EASL Clinical Practice Guidelines : Noninvasive Tests for Evaluation of Liver Disease Severity and Prognosis; Journal of Hepatology 2015
EASL/EASD/EASO	NASH	Journal of Hepatology 2016 vol 64/1388-1402 http://www.journal-of-hepatology.eu/article/S0168-8278(15)00734-5/fulltext
WHO	HCV	WHO Guidelines for Screening, Care and Treatment of Persons with Hepatitis C Infection; ISBN 978 92 4 154875 5
WHO	HBV	Guidelines for the prevention, care, and treatment of persons with chronic hepatitis B infection. 2015 WHO Algorithm of WHO recommendations of the Management of Persons with Chronic Hepatitis B infection (Page xxvi)
WHO	HCV + HIV	Management of HCV & HIV co-infection WHO 2012 HIV/AIDS treatment. Clinical Protocol for the WHO European Region Chapter 6
Baveno VI	Portal Hypertension	Expanding consensus in portal hypertension: Report of the Baveno VI Consensus Workshop: Stratifying risk and individual care for portal hypertension; 2015 Journal of Hepatology 63, 3 (743-752)
NICE (UK)	HCV	Diagnosis and Management of Chronic Hepatitis B in Children, Young People & Adults; guidance.nice.org.uk/cg165

FibroScan Accuracy

Meta Analysis of VCTE vs Biopsy

Meta-analyses of transient elastography for liver fibrosis assessment

Reference	Diagnosis	Number of studies	Number of patients	AUROC (cut-off in kPa)		
				F \geq 2	F \geq 3	F4
Talwalkar <i>et al.</i> ²⁴ (2007)	Mixed	9	2,083	0.87 (NA)	NA (NA)	0.96 (NA)
Stebbing <i>et al.</i> ²³ (2010)	Mixed	22	4,760	0.84 (7.8)	0.89 (NA)	0.94 (15.6)
Friedrich-Rust <i>et al.</i> ²² (2008)	Mixed	50	8,206	0.84 (7.7)	0.89 (NA)	0.94 (13.0)
Tsochatzis <i>et al.</i> ⁶² (2011)	Mixed	40	7,723	NA (7.3)	NA (10.2)	NA (15.0)
Chon <i>et al.</i> ²⁶ (2012)	HBV	18	2,772	0.86 (7.9)	0.89 (8.8)	0.93 (11.7)

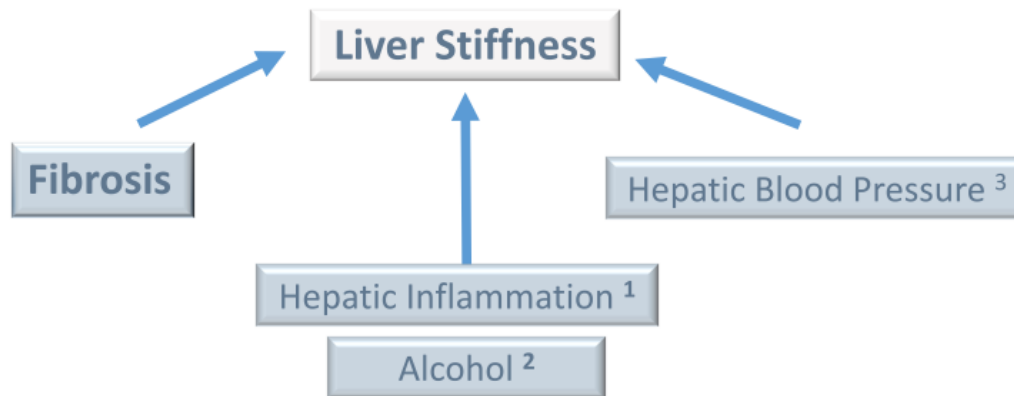
139

25,544

Peer Review Cutoff Value Reference

Disease	F0-F1	F2	F3	F4
			Significant Fibrosis	Cirrhosis
HBV	≤ 6.0	> 6.0	≥ 9.0	≥ 12.0
HCV	≤ 7.0	> 7.0	≥ 9.5	≥ 12.0
HCV-HIV	≤ 7.0	≤ 10.0	≥ 11.0	≥ 14.0
Cholestatic	≤ 7.0	≥ 7.5	≥ 10.0	≥ 17.0
NAFLD/NASH	≤ 7.0	≥ 7.5	≥ 10.0	≥ 14.0

Elastography Influencers



FibroScan (VCTE): Where Does It Stand in The US Practice: Tapper et al, Clinical Gastroenterology & Hepatology, 2015 13:27-36

1. Alanine aminotransferase-based Algorithms of Liver Stiffness Measurement by Transient Elastography (FibroScan) for Liver Fibrosis in Chronic Hepatitis B; Chan et al; Journal of Viral Hepatitis, 2009, 16, 36-44
2. Effect of Alcohol on Liver Stiffness Measured by Transient Elastography; Bardou-Jacquet et al; World Journal of Gastroenterology, 2013 Jan 28, 19(4); 516-522
3. Effect of meal ingestion on liver stiffness in patients with cirrhosis and portal hypertension; Berzigotti, A., et al; PLOS One, 2013. 8(3): p. e58742

Meal Restriction Recommendation

- Fast \geq 3 hours prior to testing
- Drinking water is acceptable



Food intake increases liver stiffness in patients with chronic or resolved hepatitis C virus infection; Mederacke, I., et al; Liver International, 2009, 29(10): p. 1500-6.

Liver Stiffness Is Influenced by a Standardized Meal in Patients With Chronic Hepatitis C Virus at Different Stages of Fibrotic Evolution; Arena et al; Hepatology, Volume 58, No 1, 2013

Intended for training only, not for promotional use.

Testing Contraindications

- Pregnancy



- Implantable electronic devices



Fibroscan Accelerates Our Treatment
Process

Initiating Treatment ~5 Patients Per
Month

Eliminate HCV 2021 *

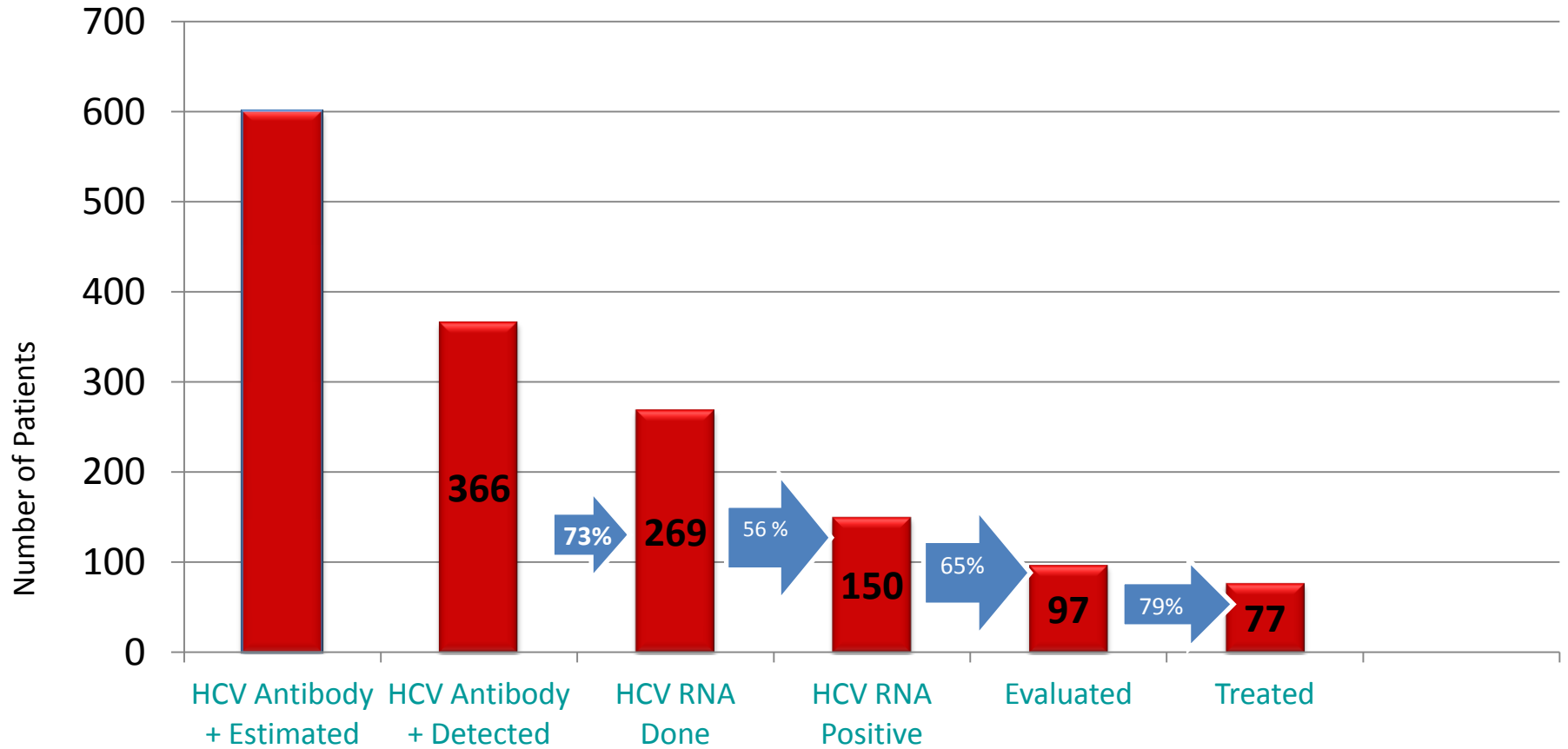
Thank You

Jessica Leston and David Stephens
NWPAlHB

Jessica Rienstra HCV Project
Coordinator

Kim Schiller HCV Project Assistant

Lummi HCV Cascade of Care



All Patients Care About Treatment

Untreated bipolar, homeless/living on sail boat, frequent drug use. YWCA, Shelter, ER.

Arrested Patient: “Not Without My Harvoni”