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BIGG ELIMINATION TRIBUTE PROJECT | MODULE 4

Building Provider Capacity for HCV Prevention Program Integration

Staging



Introductions

- Caring Ambassadors Program
- Jill Wolf, LCSW - Hepatitis C Program Director
- Co-created with Chicago Recovery Alliance (CRA) and adapted from a training conducted in October 2019



We are grateful to Abbvie and Gilead for their support of this training and education program. We are also thankful to the Chicago Department of Public Health by way of the Centers for Disease Control for supporting us with seed money that contributed to the initial curriculum development.



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In honor of Dan Bigg

- Executive Director of Chicago Recovery Alliance for 25 years
- Created system for Syringe Service Program access and Naloxone Distribution
- Awarded The Norman E. Zinberg Award for Achievement in the Field of Medicine
- Fierce HCV Elimination Advocate
- Awarded 2017 Chicagoan of the Year
- Known as the 'Godfather of Naloxone'



Photo Credit: Nigel Brunson



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Overall Project Goal

To build the capacity, confidence, and knowledge to integrate responsive hepatitis C (HCV) screening, testing, linkage-to-care/cure, and support programs into existing infrastructures.



Modules

Module 1 - Prevention & Education



Module 2 - Screening & Testing



Module 3 - Vaccination



Module 4 - Staging



Module 5 - Treatment



Module 6 - Cure



Module 7 - Wellness & Support



Staging

The purpose of this module is to illustrate the process and timeline associated with staging people living with HCV.



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Staging Objectives

Participants will be able to:

- Identify the steps needed to complete the staging process for people living with HCV
- List the resources and partners that will help accomplish and complete the staging workup process

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Staging – Nothing About Us Without Us

What can we learn from the HIV Prevention community?



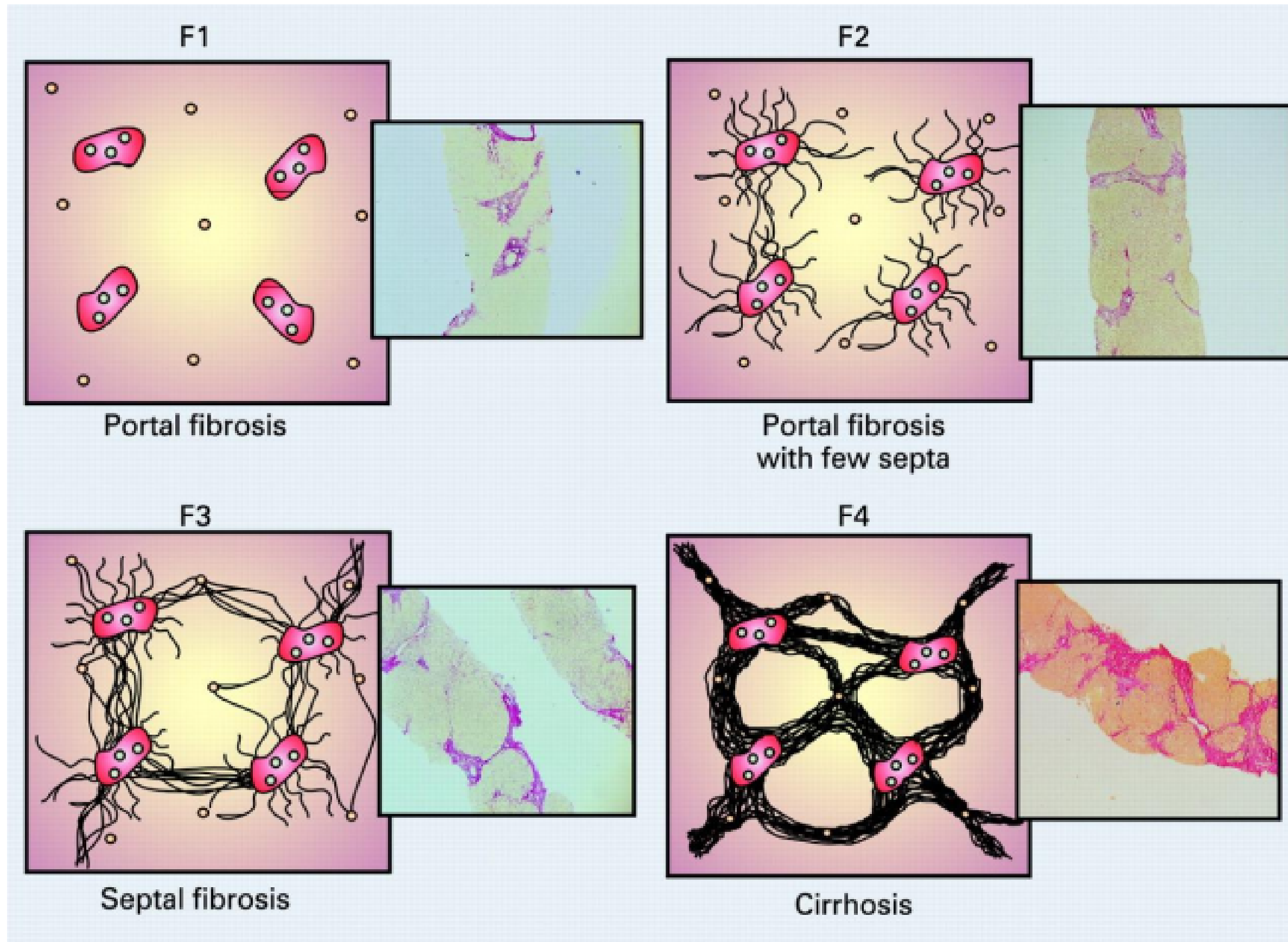
1. Staging refers to the process of identifying the level (stage) of fibrosis
2. The progression of fibrosis is variable over time and certain factors affect it:
 - a. HIV co-infection
 - b. Alcohol use
 - c. Immune suppression
 - d. Genetics
3. Prior to starting hepatitis C therapy, identify the stage/level of liver fibrosis to rule out cirrhosis



Staging - A visualization of Fibrosis



Staging - Stages of Fibrosis



Staging - Cirrhosis

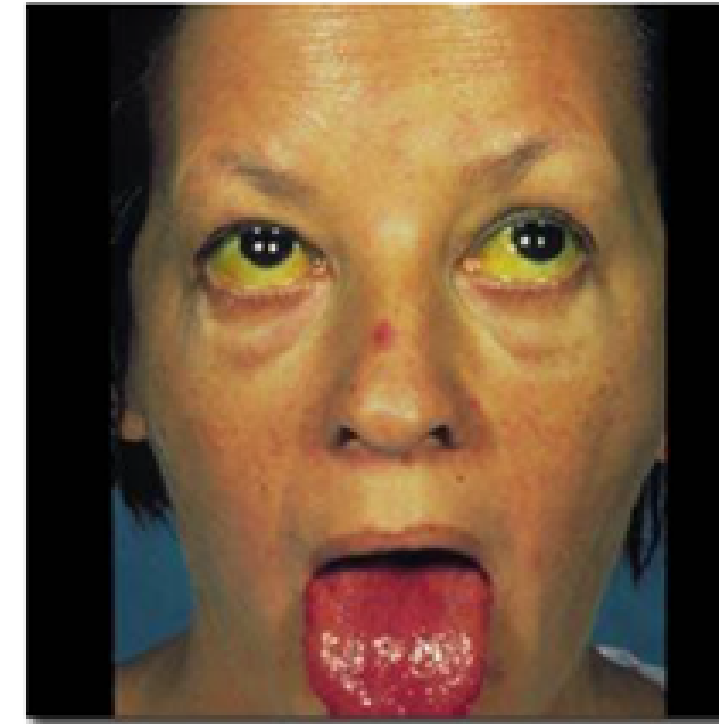
1. Diffuse fibrosis following hepatocyte destruction and nodular regeneration
2. Multiple causes
 - a. many diseases like HCV, HBV, HIV, fatty liver disease, etc. share a common 'end pathway' (i.e. cirrhosis)
3. Asymptomatic = compensated
4. Symptomatic = decompensated
 - a. Portal hypertension
 - b. Hepatic (liver) failure



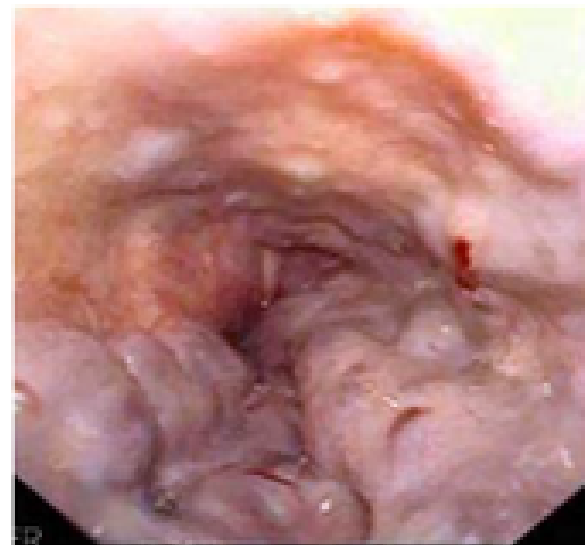
Staging - Diagnosing Cirrhosis on Physical Exam



Ascites – accumulation of fluid in the peritoneal cavity



Jaundice – Increase of bile pigments in the blood causing yellowing of eyes and skin



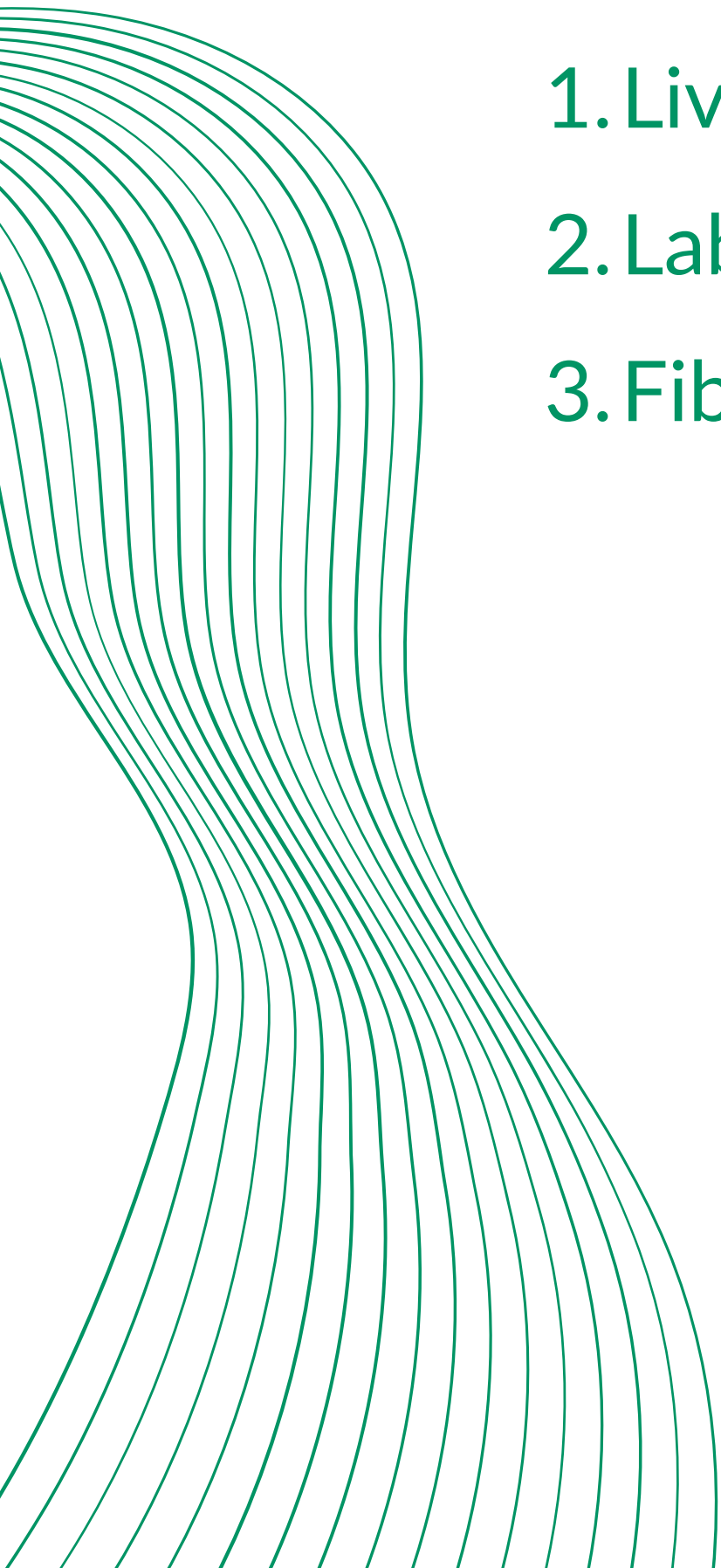
Varices – Dilation and stretching of a vein



Palmar erythema – palms become reddish in color

Staging - Imaging & Types of Imaging

1. Liver Biopsies - rarely done anymore
2. Lab studies - APRI, FIB-4, or direct markers of fibrosis
3. Fibroscan - transient elastography, measures liver stiffness



1. Uses common labs to calculate fibrosis
2. Helpful, especially when combined with other information
3. Online calculators make for easy use
4. Examples of Indirect Markers of Fibrosis - APRI & FIB-4

AST- to Platelet Ratio Index: APRI

$$\text{APRI} = \frac{\frac{\text{AST Level}}{\text{AST (Upper Limit of Normal)}}}{\text{Platelet Count (10}^9\text{/L)}} \times 100$$

Fib-4

<http://gihep.com/calculators/hepatology/fibrosis-4-score/>

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



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Staging - Labs & Indirect Markers of Fibrosis

APRI

- validated in HIV/HCV co-infection
- Cutoff = 0.7
 - 77% sensitivity and 72% specificity in detecting **F2 or greater**
- Cutoff = 1.0
 - 76% sensitivity and 72% specificity in detecting **cirrhosis**
- The HIGHER the number, the more likely the patient has fibrosis
- LIMITATION: Hard to differentiate between stages of fibrosis

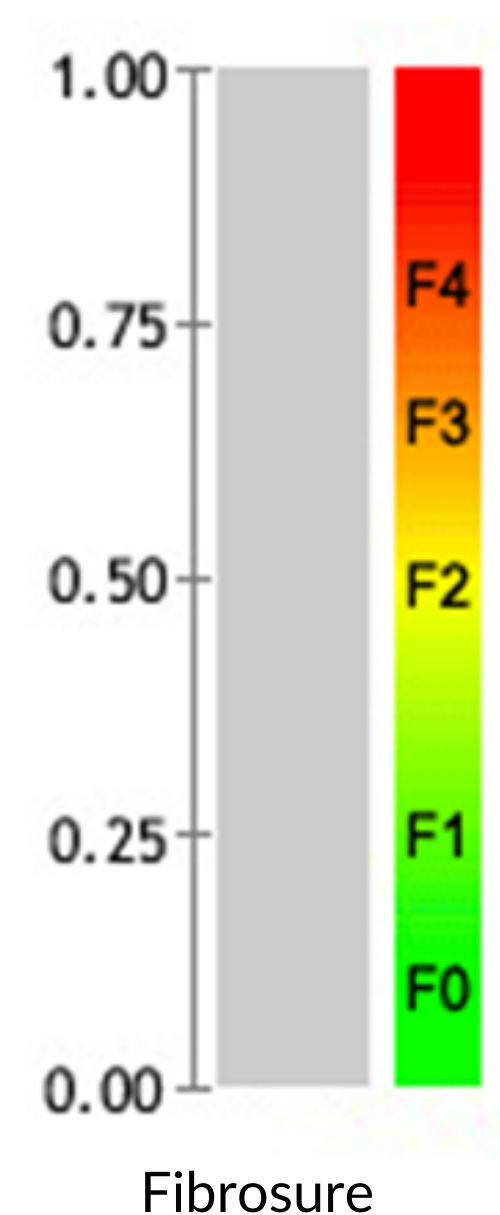
FIB-4

- Cutoff = <1.45
 - 90% negative predictive value for advanced fibrosis (F3-F4)
- Cutoff = >3.25
 - 97% specificity and 65% positive predictive value for advanced fibrosis



- Specialized labs that are typically sent out
- Directly measures levels of liver fibrosis

Score (original reference)	Variables	Performance in HCV patients ¹					
		Significant fibrosis ($\geq F_2$)			Cirrhosis ($\geq F_4$)		
		Median AUROC	Median sensitivity ²	Median specificity ²	Median AUROC	Median sensitivity ²	Median specificity ²
FibroTest ^[53]	Age, sex, serum haptoglobin, α 2-macroglobulin, apolipoprotein A1, GGT, and total bilirubin	0.79	92%	96%	0.86	85%	81%
ELF ^[56]	Age, TIMP-1, PIIINP and hyaluronic acid	0.81	85%	70%	0.88	-	-
Fibrometer ^[61]	Platelet count, prothrombin index, AST, α 2-macroglobulin, hyaluronic acid, blood urea nitrogen and age	0.82	69%	81%	0.91	-	-
FIBROSpect II ^[63]	TIMP-1, α 2-macroglobulin and hyaluronic acid	0.86	80%	70%	-	-	-
Hepascore ^[66]	Age, sex, α 2-macroglobulin, hyaluronic acid, GGT and total bilirubin	0.79	66%	79%	0.89	72%	86%



Fibroscan



Staging - Transient Elastography

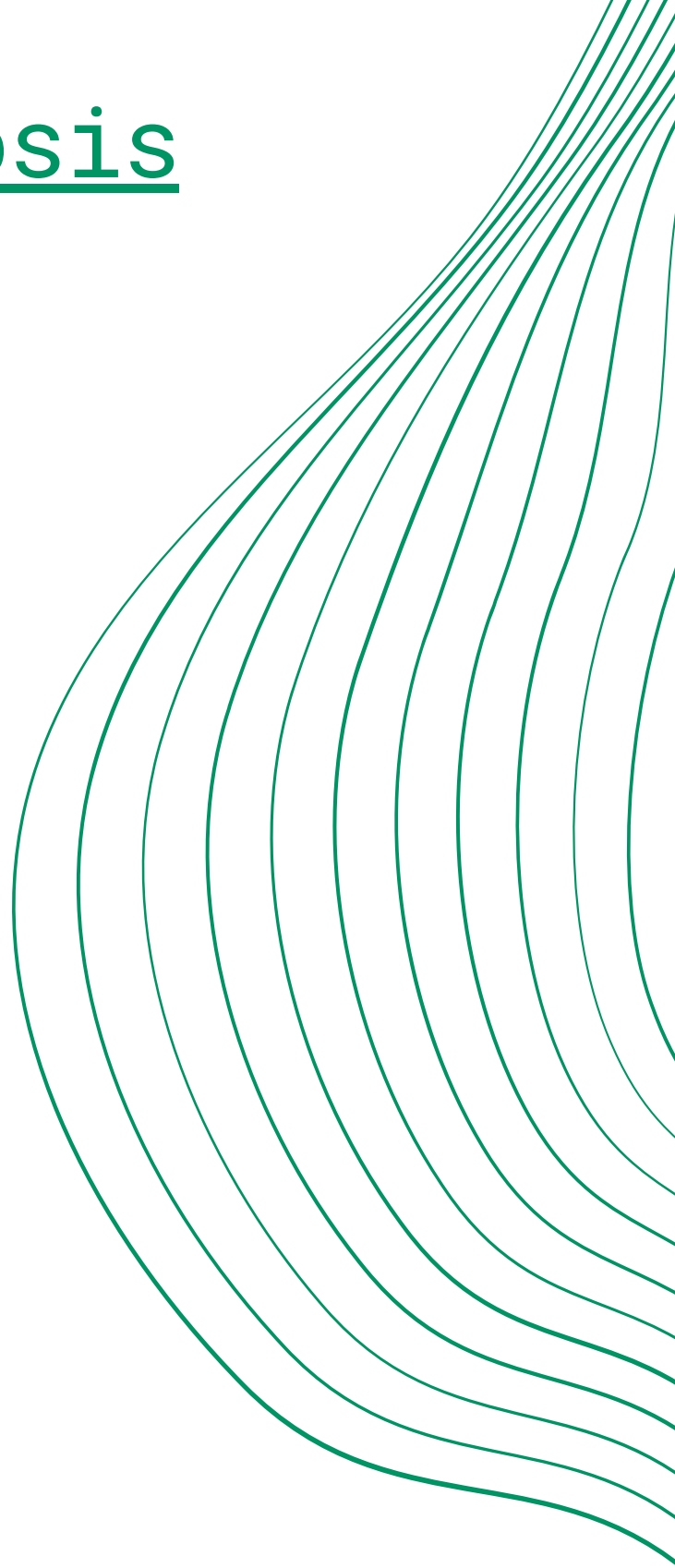
	≥F1	≥F2	≥F3	F4
Liver stiffness cut off (kPa)	5.3	7.4	9.1	13.2
Sensitivity (%)	84.99	80.32	88.8	93.75
Specificity (%)	73.21	83.97	88.3	93.21
Positive Predictive Value (%)	90.4	90.1	84.5	86.5
Negative Predictive Value (%)	19.6	70.2	91.7	97.0



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Staging - Steps to Assessing Fibrosis

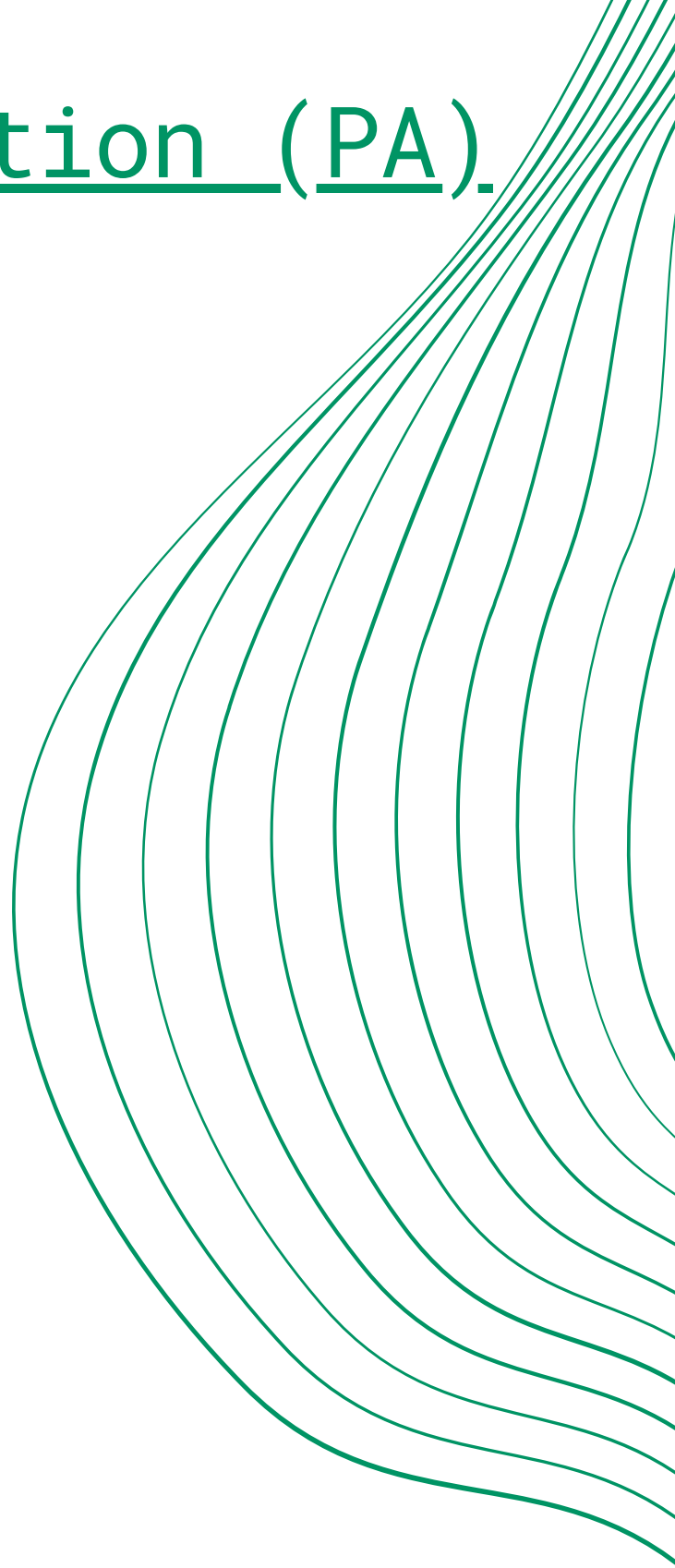
1. Rule out clinical evidence of cirrhosis
 - a. Labs
 - b. Radiology
 - c. Exam
2. Noninvasive markers
 - a. APRI
 - b. Fib 4
 - c. Fibrosure
 - d. Fibrospect
3. If further delineation is needed >>>>> Liver Biopsy
 - a. Not needed in many (maybe most) situations



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Staging - Teeing Up the Prior Authorization (PA).

1. Identify patient's insurance coverage – Rx, prescription
2. Determine eligibility & ensure there's no cap for Rx costs
3. Obtain prior authorization paperwork from insurance
4. Follow PA instructions and gather lab data
5. Compile all necessary information on PA (labs, imaging, etc.)
6. Fax PA form with documentation



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Staging – Teeing Up the Prior Authorization (PA).

as indicated by Illinois' HFS PA Criteria

1. Fibrosis

- a. May be serologic – FibroTest, FiboSure, FibroMeter
- b. May be Imaging – FibroScan or Biopsy (don't do a biopsy!)

2. Labs taken w/in 3 months from PA date

- a. Genotype
- b. Baseline Quant RNA (w/in 1 year of PA request)
- c. ALT and AST
- d. CBC
- e. GFR
- f. INR, albumin, and bilirubin (Stage 4 only)
- g. Negative HBV screening
- h. If positive, quantitative HBV DNA

3. Specialist Consult Letter

4. Letter of Commitment

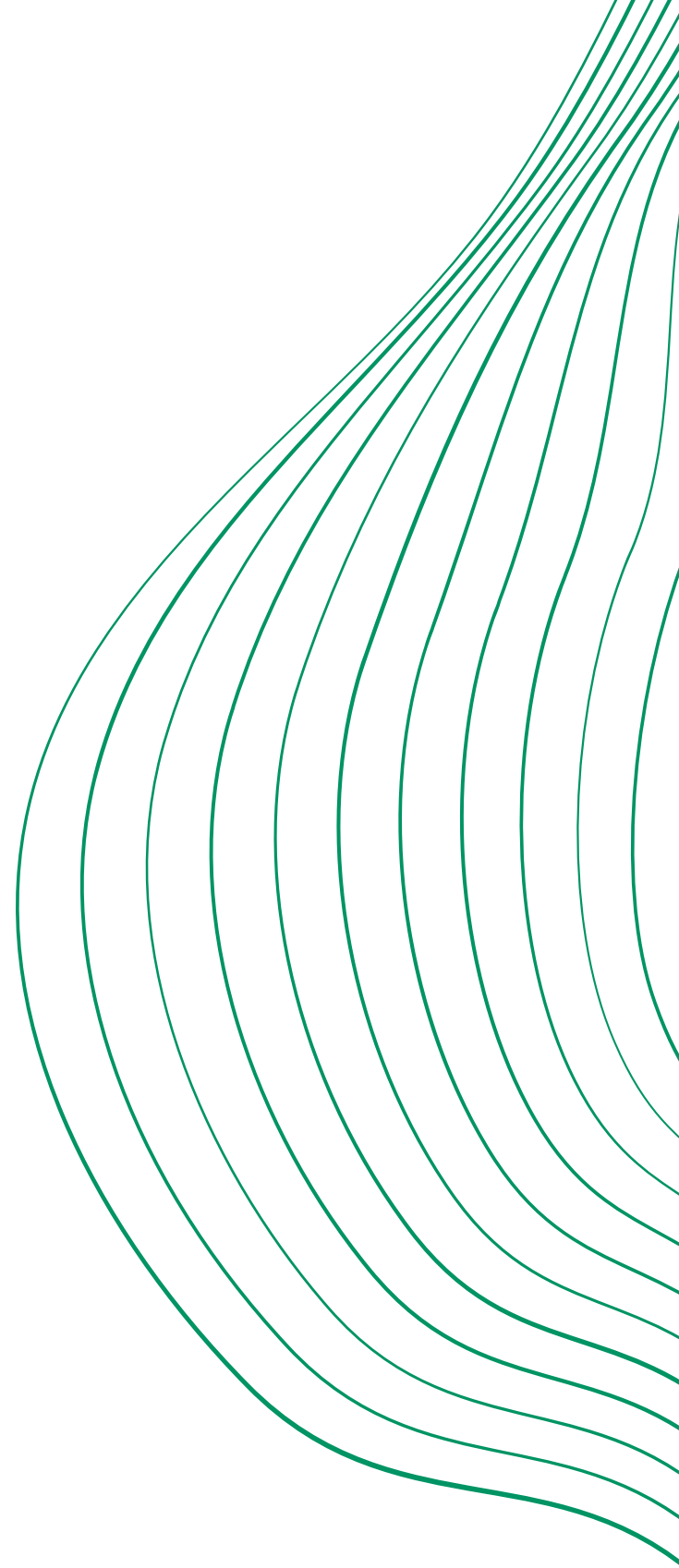
5. Address Drug-Drug Interactions – Check Liverpool Hepatitis Website



1. Optional Letters/Scenarios, where appropriate
 - a. SUD
 - b. Prior Treatment b/c of non-adherence
2. Ongoing Lab Submission
 - a. Start of treatment
 - b. w/in 8 weeks of starting treatment
 - c. 12 weeks post-treatment
 - d. 24 weeks post-treatment



1. Treatment History
2. Addressing substance use disorders
3. Transmission
4. Reinfection
5. Family testing and exposure
6. Timing for setting the stage for successful therapy
7. Stigma
8. Health & Insurance literacy



1. AASLD Treatment Guidelines

a. www.HCVGuidelines.org

2. Calculators

a. APRI

b. FIB-4

3. Prior Authorization Check Lists

4. Specialty Pharmacy

5. ECHO

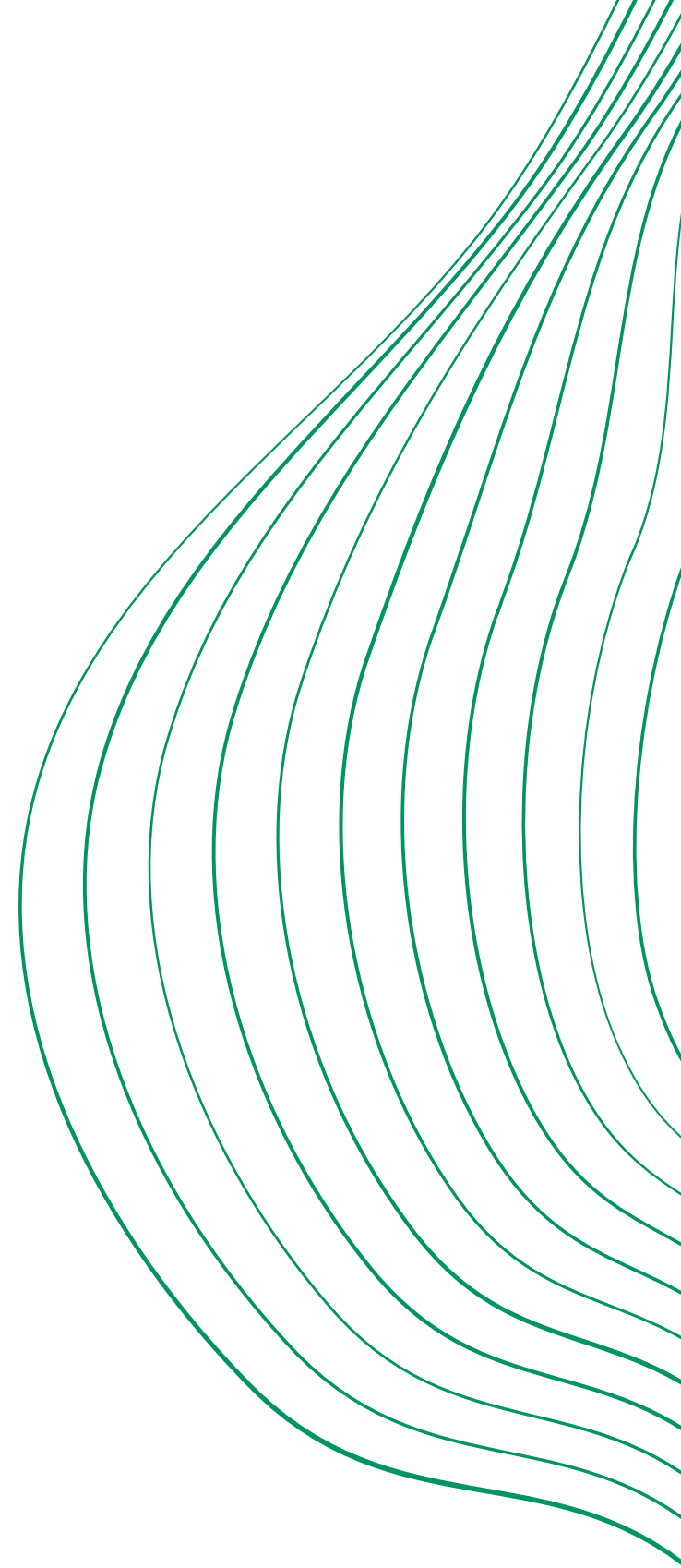
a. HCV

b. Opioids



Staging - What's Changed?

1. Treatment has gotten easier
 - a. Less side effects
2. More treatment options
3. Treatment is extremely effective
4. More patients are being allowed treatment– less denials
5. Insurance Restrictions have loosened



In conclusion...

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What's Next?

- Next Module is: Treatment
- About 1 hour/1 CEU
- The purpose of the next module will be to explain the HCV treatment process and clarify HCV treatment goals.

Obtaining CEU's & Attendance Certificates

- *Don't forget* to take the pre and post-test surveys to receive CEU's or Certificates of Completion!

Access to Tools

Access to tools, resources, slides, and activities can all be found at
<https://hepcchallenge.org/biggl>

Questions?

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