Interpretation of FibroScan

TE & CAP

Transient Elastography (TE)

- TE is reliable for the diagnosis of cirrhosis in patients with chronic liver diseases.
- Most **extensively studied and validated** imaging technique, with **high intra- and inter-observer reproducibility**.
- TE is **better at "ruling out"** than "ruling in" cirrhosis (NPV = 96% and PPV = 74%)
- Correctly classifies cirrhosis in 80 to 98% of patients (AUROC 0.8-0.99); less accurate for lesser fibrosis.
- **Cut-offs are different by diagnosis**.
- TE is better validated in viral (HCV, HCV/HIV, HBV) than in NAFLD.
  - If ALT higher than 5 x ULN, repeat test after hepatitis is controlled.
- In Alcoholic Liver Disease the values are not very reliable while actively drinking.
  - If AST is > 100 U/mL, repeat the Test after **2 weeks or more of abstinence**.

Parameters Needed for Correct Interpretation of TE & CAP

- Interquartile Range IQR/ median value (<30%),
- Serum aminotransferases levels (<5 x ULN),
- Absence of extra-hepatic cholestasis,
- Absence of right heart failure, or other causes of congestive liver
- Absence of ongoing excessive alcohol intake,
- BMI (use **XL Probe** above ***BMI of 30*** kg/m^2 or if ***skin-to-capsule distance is >25 mm***),
- Presence of Diabetes Mellitus
- Presence of NAFLD or NASH

UofL TE Interpretation Summary

Modified from: Bonder A, Afdhal N. Current Gastroenterology Reports 2014; 16:372, Lim JK et al. Gastroenterology 2017; 152:1536-1543, Moreno C et al. J of Hepatology 2019(70): 273-283; Wu S et al. Hepatology International (2019) 13:91–101

	F0-F1 (kPa)	F2 (kPa)	F3 (kPa)	F4 (kPa)
HBV	</= 6	6.1 to 9	9.1 to 10.9	**>/= 11***
HCV	</= 7	7.1 to 9.4	9.5 to 12.4	**>/= 12.5***
HCV-HIV	</= 7	7.1 to 10	10.1 to 13.9	>/= 14
Cholestatic Liver Disease	</= 7	7.1 to 9.9	10 to 16.9	>/= 17
Autoimmune Hepatitis	</= 6.2	6.3 to 8.4	8.5 to 12.3	>/= 12.4
NAFLD/NASH	</= 7	7.1 to 9.9	10 to 13.9	>/= 14
Alcoholic Liver Disease (Abstinent > 2 weeks and without alcoholic hepatitis (AH))	</= 6	6.1 to 7.9	8 to 12.4	**>/= 12.5*** [>/= 30 kPa if with AH]
High Probability of varices				**>/= 19.5***
Low probability of CSPH				**< 17***

HBV: -Liver Biopsy if it could change management
-With NORMAL ALT, consider treating if > 9 or 11 kPa (vs Bx)

HCV: after recent SVR, TE </= 9.5 kPa identifies patients that can be discharged (no HCC risk)

Baveno VI Consensus recommended:
TE >/= 20 kPa, or Platelets < 150,000.
In PBC cut-off is TE >/= 17 kPa.

***AGA 2017 Guideline**

FibroScan "Controlled Attenuation Parameter" (CAP) Interpretation

Meta-analysis of 2735 patients comparing histology and CAP with BMI </= 35: **Karlas T et al. J Hepatol. 2017 May;66(5):1022-1030****

CAP measures the increased **attenuation** of ultrasound waves when travelling through steatotic hepatic tissue, compared to normal liver.
Interpretation is based in studies of CAP results paired with liver biopsy samples.

Steatosis Degree	S0	S1	S2	S3
Affected Hepatocytes (%)	< 10%	10-33%	34-66%	> 66%
CAP (dB/m)	< 248	248-267	268-279	> 280

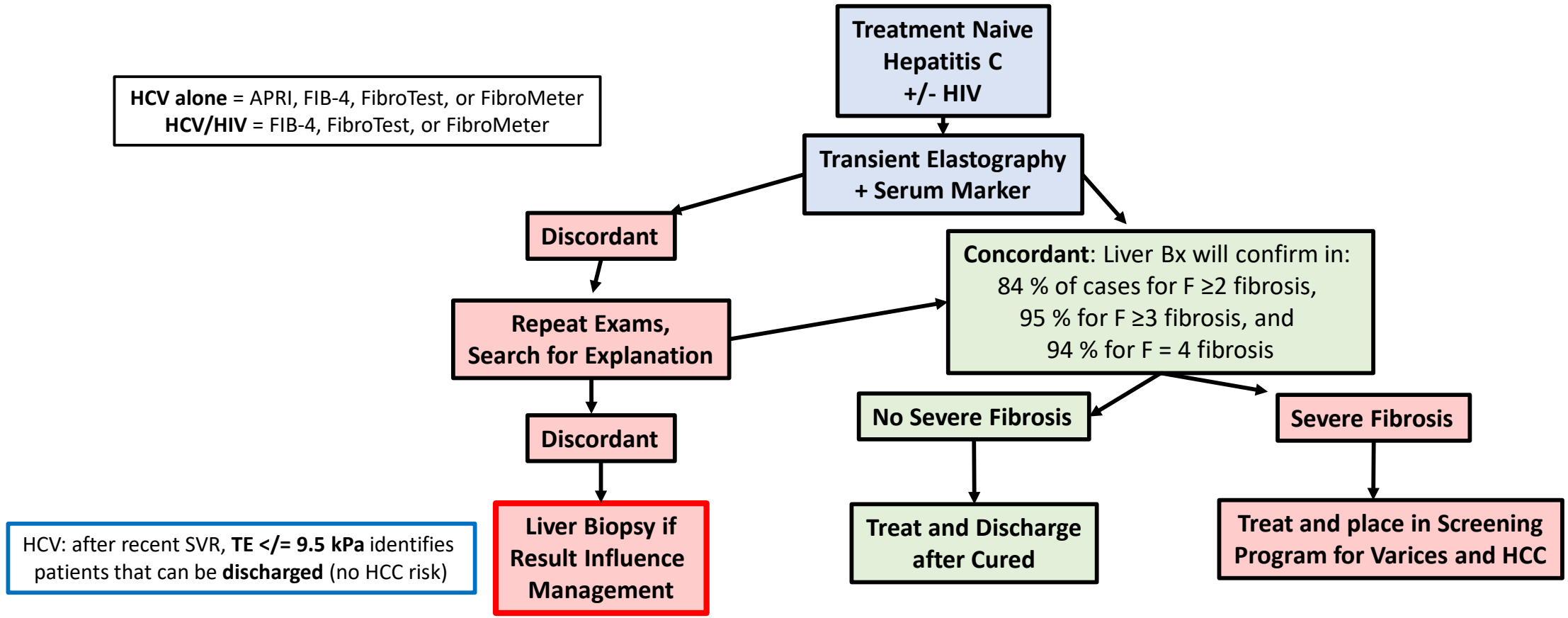
CORRECTIONS:
Deduct 10 dB/m for NAFLD/NASH
Deduct 10 dB/m for Diabetes
Deduct 4.4 dB/m for each BMI point below 25 (max 22 dB/m)
Add 4.4 dB/m for each BMI point above 25 (max 22 dB/m)

**Patients with BMI > 35 were excluded

CAP validity is lower if the IQR of CAP is ≥ 40 dB/m (AUROC 0.77 vs 0.9 if < 40)

Sequential Algorithm for Fibrosis Evaluation (SAFE) in Hepatitis C

Modified from: Journal of Hepatology 2015 vol. 63; 237–264 and Gastroenterology 2017 Vol. 152, 1536–1543



FibroScan (TE) in Hepatitis C

- When the elastography and FibroTest (e.g.: Fibro Sure, Fibro Test-ActiTest) results agreed, liver biopsy examination confirmed the stage of fibrosis in:
  - 84 percent of cases for F ≥2 fibrosis,
  - 95 percent for F ≥3 fibrosis, and
  - 94 percent for F = 4 fibrosis

Transient Elastography (TE) in HCV

In patients with **active** HCV:

- TE **>/= 12.5 kPa** reliably identifies **cirrhosis** (< 5% False Negative rate).

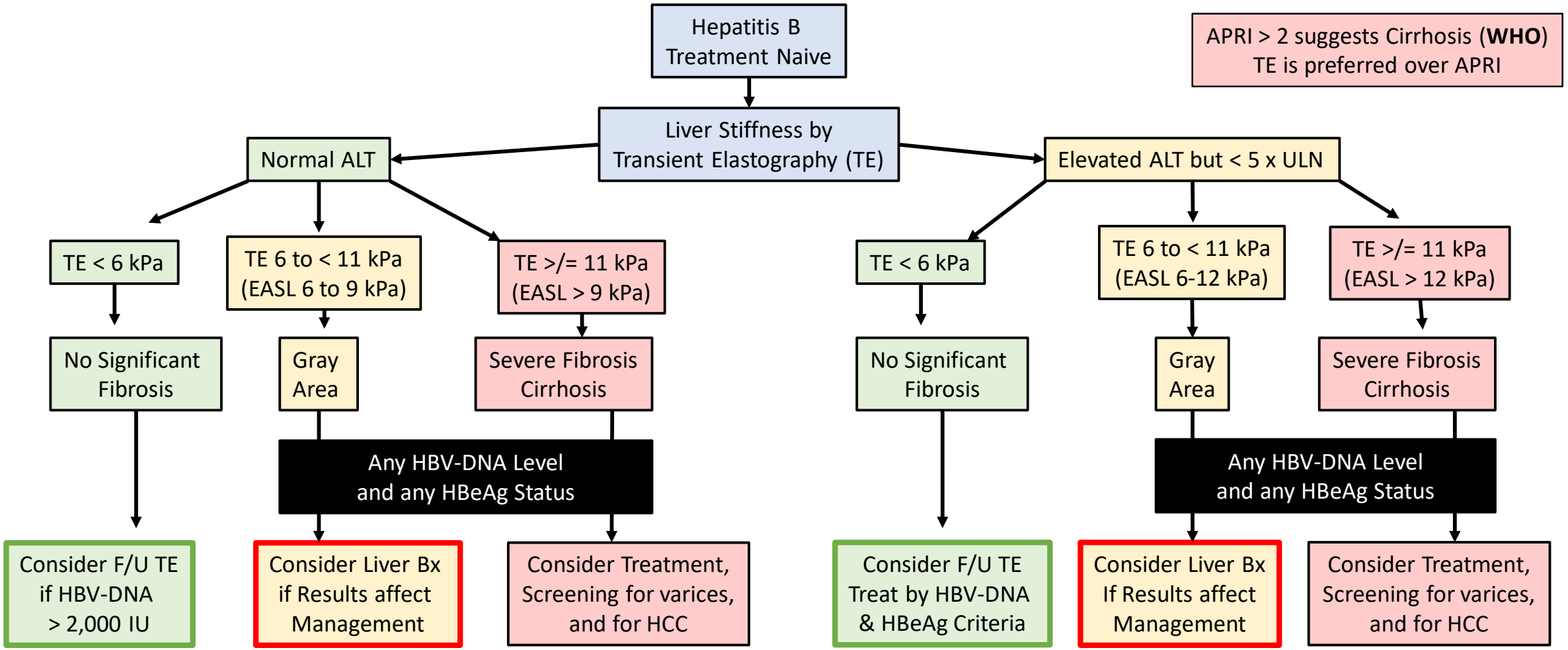
In patients with HCV **after SVR**:

- TE **< /= 9.5 kPa**, shortly after SVR, reliably identifies patient who **can be discharged** (< F3, with < 7% False Negative rate; no need for surveillance).

MR elastography is NOT superior to TE in patients with Hepatitis C.

Sequential Algorithm for Fibrosis Evaluation (SAFE) in HBV by ALT Elevation & TE

Modified from: Journal of Hepatology 2015 vol. 63; 237–264 and Gastroenterology 2017 Vol. 152, 1536–1543



Transient Elastography (TE) in HBV

In patients with HBV:

- TE **>/= 11 kPa** in USA reliably identifies **cirrhosis** (AGA 2017) (In Europe: > 9 kPa with normal ALT, or > 12 kPa with elevated ALT < 5 x ULN).
  - False negative rate < 5% (sens 81%; specif 83%);
  - All patients with cirrhosis **should be treated**.
- If **ALT is elevated** but < 5 x ULN, either HBeAg(+) or HBeAg(-), and independently of HBV-DNA level:
  - TE with **kPa >/= 6 to < 11** in USA (>/= 6 to 12 kPa in Europe) should lead to **liver biopsy**, if likely to change management.

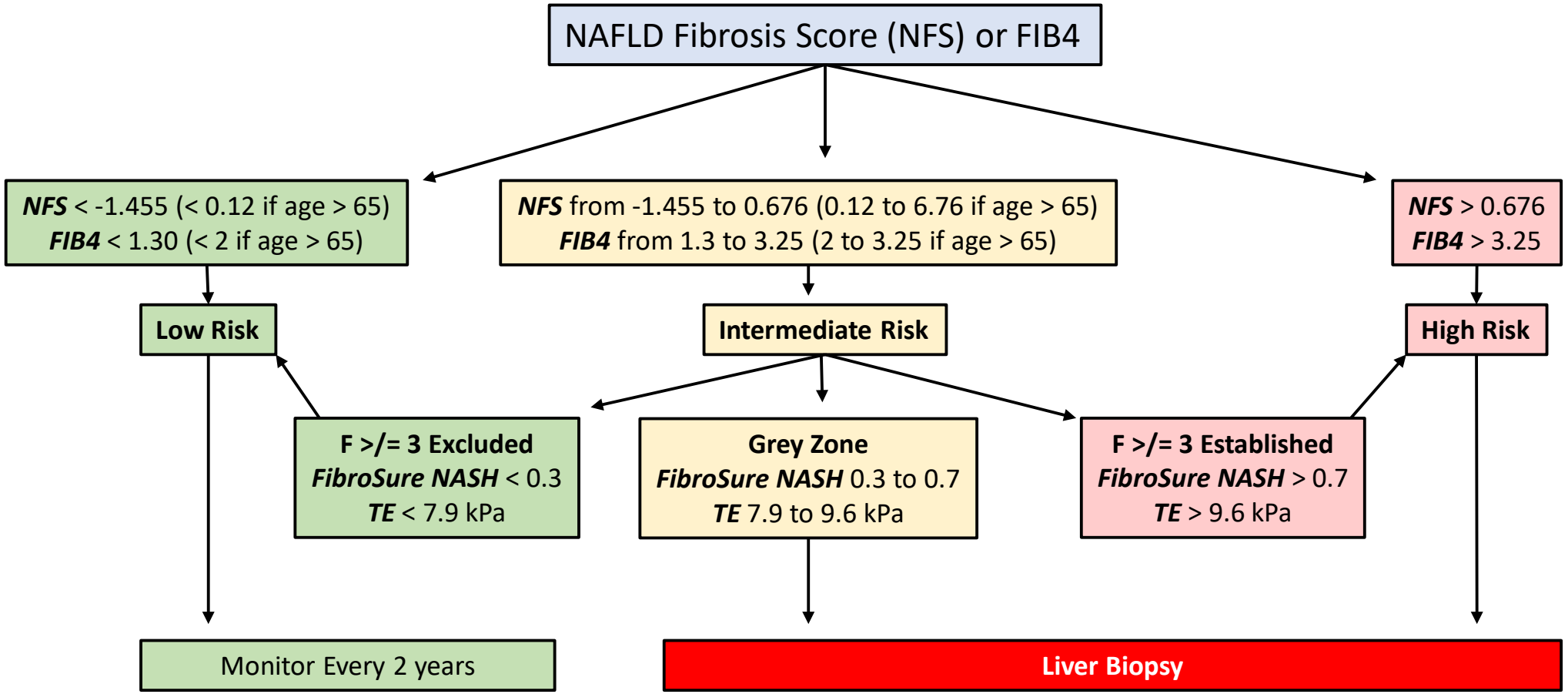
Transient Elastography (TE) in HBV

In patients with HBV:

- If **ALT is normal** but TE **> 11 kPa** in USA (AGA 2017 guidelines) (> 9 kPa in Europe by EASL 2015), strongly consider **therapy** + **varices surveillance** (> 19.5 kPa)
  - All patients with **cirrhosis should be treated**.
- In **patients older than 35** with **normal ALT**, and either HBeAg(+) or HBeAg(-):
  - TE with **>/= 6 to < 11 kPa** in USA (likely >/= 6 kPa to 9 kPa in Europe) should lead to **liver biopsy** to decide if treatment is needed (EASL 2015; AGA 2017).

Sequential Algorithm for Fibrosis Evaluation (SAFE) in NAFLD

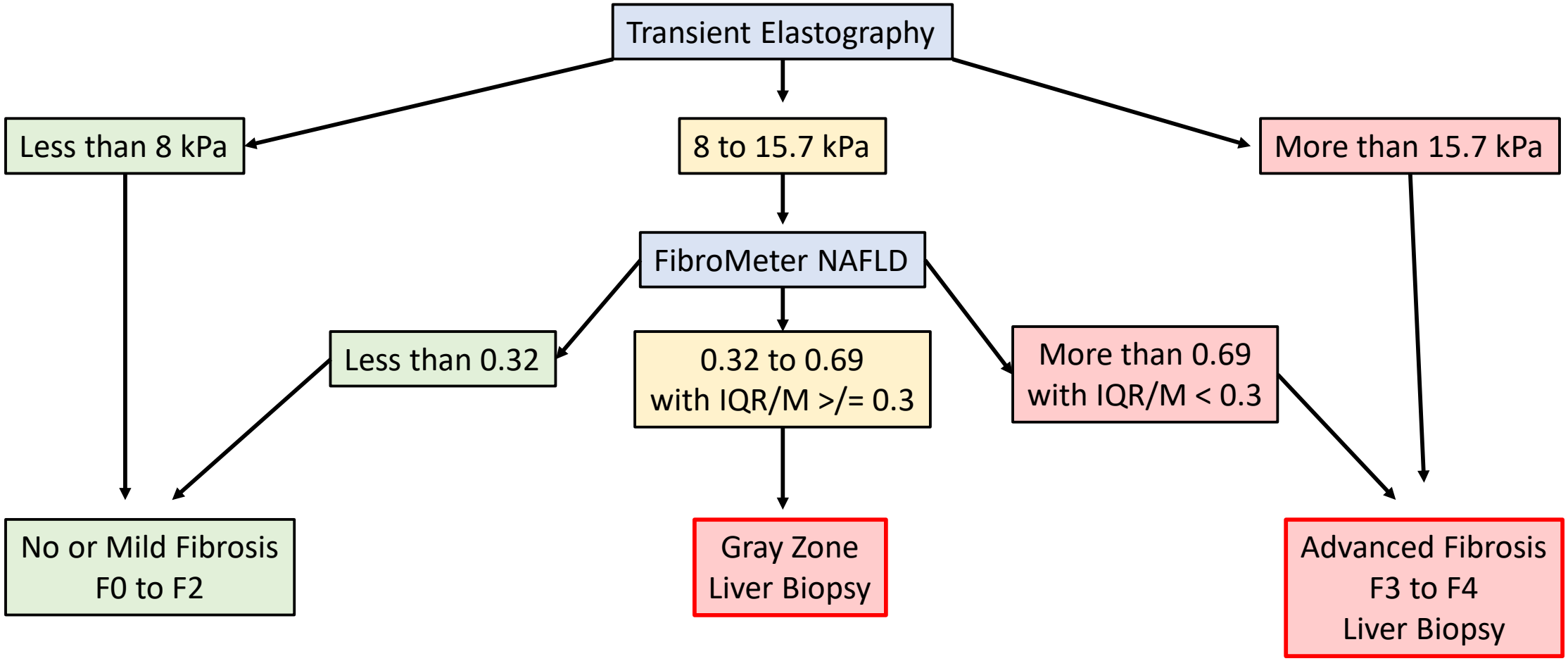
Modified from: J Hepatol 2016; 64:1388-1402; J Hepatol 2019; 71:389-396; Am J Gastroenterol 2017;112:740-751



TE = Transient Elastography

SAFE for NAFLD with Transient Elastography + FibroMeter

Modified from: Journal of Hepatology 2019 vol. 71: 389–396



Transient Elastography (TE) in NAFLD

In patients with NAFLD: TE nor APRI nor FIB-4 are reliable enough to diagnose cirrhosis

- In **populations with high prevalence of cirrhosis** (subspecialty clinic) **MR Elastography** is superior to TE to diagnose cirrhosis in NAFLD (less “False Positives”).
- **Liver Biopsy** is needed for accurate diagnosis/staging, and before drug-therapy.

Transient Elastography (TE) in ALD

In **Alcoholic Liver disease** (not actively drinking >/= 2 weeks & AST < 100) a cut-off of **12.5 kPa** detects **cirrhosis** with low "false negative" rates (< 1.5%) but relatively high "false positive" rates (27.5% and 20.3%) in low vs high prevalence groups, respectively, most of the **false (+) being F3**.

TE is NOT reliable to diagnose cirrhosis in Acute Alcoholic Hepatitis.

In **Alcoholic Hepatitis**, TE **> 30 kPa** indicates **cirrhosis**.

Transient Elastography (TE) in Cirrhosis

In patients with cirrhosis, a TE **>/= 19.5 kPa** identifies patients at **higher risk of esophageal varices** (AGA Guidelines, 2017).

In **PBC**, a TE **>/= 17** identifies patients at **higher risk of esophageal varices** (AASLD PBC-Guidance, 2018)

- Baveno VI Consensus recommended TE > 20 kPa or platelet count < 150,000 as triggers for screening EGD
- A TE of **>/= 50.7 kPa** suggests **high risk of variceal bleed**.

A TE **< 17 kPa** is indicative of **absence of "clinically significant portal hypertension"** (no varices) with misclassification rate < 6.8%.