TRAINING MANUAL FOR TREATMENT ADVOCATES HEPATITIS C VIRUS & COINFECTION WITH HIV **Treatment Action Group**

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SECTION 6: HCV DIAGNOSTICS FOR MAKING TREATMENT DECISIONS

- DAAs can achieve a sustained virological response
 (SVR) in over 95% of people. An SVR means a person
 has no detectable HCV after completing the treatment.
- Effective DAA combinations, such as sofosbuvir/ daclatasvir and sofosbuvir/velpatasvir, are becoming accessible for more people, genotyping is becoming less relevant.



HCV Genotyping and Treatment Decisions

- Seven hepatitis C genotypes (subtypes of the virus), numbered 1 through 7.
- Genotype 1 is most common in the United States. People with genotype 1 are more likely to have high hepatitis C viral loads.
 - Genotyping may still be relevant if you have cirrhosis; used in high-income countries, where they are more widely available and covered by insurance.
- Genotype 3 is most common in India, Myanmar, Thailand, and other parts of Asia, the Middle East, and North Africa.
 - People who have genotype 3 and cirrhosis are more likely to have *steatosis* (fat in the liver); this can make treatment less effective.



Cirrhosis Can Be Diagnosed Without a Liver Biopsy

- Liver specialists, particularly in Europe, operate a machine called *FibroScan* that looks at liver stiffness using sound waves. Also determine the level of liver damage and degeneration of liver cells.
- Difficult to diagnose mild or moderate liver disease without doing a biopsy, however, and FibroScan is not widely available in most countries.
- Non-invasive blood tests look for cirrhosis:
 - APRI, or aspartate aminotransferase (AST) to platelet ratio index, is a formula used to determine the level of cirrhosis.
 - A group of blood tests, or liver function tests, do not actually measure liver function, nor do they predict or tell someone how much liver disease they have.
 - Check the level of liver enzymes and indicate other aspects of the health of the liver

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Track Your Lab Work (1/2)

Lab Tests	Date	Date	Date	Normal Ranges
CD4 count				From 0 to 1,600 cells/mm3
HIV viral load				From undetectable to over 1 million IU/mL
HCV viral load (HCV RNA)				From undetectable to over 10 million IU/mL
ALT (or SGPT)				Women: 19 IU/L Men: 30 IU/L Alanine aminotransferase (ALT) is made by the liver. When ALT is abnormally high, it may be a signal that the liver inflamed or damaged, especially if it stays high over time. ALT is not a good indicator of liver damage, since levels can be normal in people with serious liver damage, and they may go up and down in people with HCV. Certain treatments, including some ARVs, may increase ALT.
AST (or SGOT)				Women: 9 to 25 IU/L Men: 10 to 40 IU/L Aspartate aminotransferase (AST) is made in the heart, intestines and muscles. It does not always show liver damage by itself; AST is used with other tests to monitor liver inflammation and damage.
ALP				Women: 30 to 100 IU/L Men: 45 to 115 IU/L Alkaline phosphatase (ALP) is found in tissues throughout the body, including in the liver. Abnormally high ALP is a signal of diseased or damaged tissue. When ALP that comes from the liver is abnormally high, it is a sign of liver disease.
APRI				The lab results are used to plug in to a formula to determine the AST to platelet ratio index to predict cirrhosis. An APRI score greater than 0.7 has a sensitivity of 77 percent and specificity of 72 percent for predicting significant liver fibrosis.
GGT				Women: <45 IU/L Men: <65 IU/L Gamma-glutamyl transferase (GGT) is made in the bile ducts, the tubes carrying bile from the liver to the gallbladder and intestines. Liver disease, heavy drinking, and some medications can cause abnormally high GGT levels.



Track Your Lab Work (2/2)

Lab Tests	s	Date	Date	Date	Normal Ranges
					0.0 to 0.4 mg/dL (U.S.)
Bilirubin (direct)					0 to 7 umol/L (SI units)
				Direct bilirubin is produced in the liver. If bile ducts are blocked, direct bilirubin will seep into the bloodstream (and sometimes the urine). Liver disease, or certain medications, may increase the level of direct bilirubin in the bloodstream.	
					0.0 to 1.0 mg/dL (U.S.)
Bilirubin (total)	(total)				0 to 17 umol/L (SI units)
	(lotal)				Indirect bilirubin travels from the bloodstream to the liver, to be broken down into a form that dissolves in water. Abnormally high levels of indirect bilirubin may signal liver disease.
Albumin					3.1 to 4.3 g/dL (U.S.)
					31 to 43 g/L (SI units)
					Albumin carries medications, hormones, and waste products through the bloodstream and keeps fluid in the body. Abnormally low albumin levels are a sign of liver damage.
PT					11 to 13.5 seconds (1 to 2 times above this range is abnormal: INR 2 to 3)
					Prothrombin time (PT) is a measurement of how long it takes for blood to clot. The liver helps produce platelets, which clot blood. A longer PT means that the liver is not functioning normally.



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Discussion Questions:

- 1. Are all the different HCV tests for making treatment decisions available? Is cost a problem? Are the tests covered under your insurance plan?
- 2. Do doctors take the time to explain test results?

Action Steps:

- 1. What kind of tools can help people understand test results?
- 2. What can we do to increase access to expensive tests?
- 3. With whom can we make alliances to increase our understanding of and access to these important tests?