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

TAG

SECTION 8: HOW TO TELL IF HCV TREATMENT IS WORKING AND SIDE EFFECTS

- The main goal of HCV treatment is to completely get rid of, or cure, the virus.
- Treating—and curing—HCV can reduce the risk of cirrhosis, liver cancer, liver failure, and liver disease—related deaths.
- Regular monitoring for liver cancer after successful treatment is important, especially for people with cirrhosis—they are at risk of liver cancer.
- A viral load test is usually performed 4 weeks after starting treatment, even though a detectable HCV viral load at week 4 is not predictive of HCV treatment outcome.
- Evidence suggests the viral load test at week 4 is not necessary, and provides an opportunity to reduce the number of lab tests, which can be costly.



- Testing HCV viral load 12 weeks after finishing treatment is the best measure for a sustained virologic response.
- An SVR12 means that a person has no detectable HCV after 12 weeks of treatment has been completed.
- An SVR12 is considered a cure.
 - AASLD, EASL, and WHO guidelines all recommend HCV viral load testing at week 12 after treatment has ended.

WHO Framework for Frequency of Monitoring of People Undergoing HCV Treatment, Based on Regimen Type

Time	DAAs alone			DAA + ribavirin			DAA + pegylated interferon + ribavirin			
	FBC, renal, liver function	Adherence, side effects	HCV viral load	FBC, renal, liver function	Adherence, side effects	HCV viral load	FBC, creatine, ALT	Thyroid function	Adher- ence, side effects	HCV viral load
Baseline	~		~	~		~	~	~		~
Week 1				~	~		~		~	
Week 2	~	~		~	~		~		~	
Week 4	~	~		~	~		~		~	
Week 8				~	~		~		~	
Week 12				~	~		~	~	~	~
Week 12 after end of treatment			v	~		~	~	~		~
Week 24 after end of treatment										~

ALT: alanine aminotransferase (a liver enzyme); FBC: full blood count

Source: World Health Organization. Guidelines for the Screening, Care and Treatment of Persons with Chronic Hepatitis C Infection; 2016 April.



Side Effects of HCV Treatment (1/2)

Common side effects, or "adverse reactions," of DAAs include:

- **Daclatasvir (Daklinza™, or DCV):** Fatigue, headache, and nausea in regimens with or without RBV.
- Elbasvir/grazoprevir (Zepatier®, or EBR/GZR): Headache, nausea, insomnia, and diarrhea.
- Ombitasvir/paritaprevir/ritonavir and dasabuvir (Viekira Pak®): Itchy skin (pruritus); fatigue, nausea, and trouble sleeping (insomnia) more common when combined with RBV; increases in ALT (a liver enzyme, most frequently in people also using estrogen therapy), and bilirubin (most frequently in people using RBV).
- Simeprevir (Olysio®, or SMP): Rash and sun sensitivity (photosensitivity), which may be more severe in people of East Asian ancestry; fatigue, headache, nausea, insomnia, and pruritus.
- Sofosbuvir (Sovaldi®, or SOF) with or without ledipasvir (Harvoni®, or SOF/LED): fatigue, headache, insomnia, and nausea; abnormal heart rhythm (bradyarrhythmias) in people taking SOF at the same time as the medicine amiodarone (used to treat abnormal heart rhythms), so these medications should not be used together.



Side Effects of HCV Treatment (2/2)

- Sofosbuvir/velpatasvir (Epclusa®, or SOF/VEL): Headache and fatigue; additional side effects, which are more common in people with decompensated cirrhosis, include anemia, headache, insomnia, and diarrhea.
- Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®, or SOF/VEL/VOX):
 Headache, tiredness, diarrhea, and nausea. This combination should not be taken with amiodarone, used to treat certain heart problems, as it may cause slow heart rate. In some cases the slow heart rate has led to death or the need for a pacemaker when amiodarone is taken with medicines containing SOF.
- Glecaprevir/pibrentasvir (Mavyret™, or G/P): Headache, fatigue, and nausea. People with severe hepatic impairment (Child-Pugh C), or who take atazanavir or rifampin should not use this treatment. People who take carbamazepine, efavirenz-containing regimens, or St. John's wort are not recommended to take this treatment as it could be harmful and have reduced therapeutic benefits.
- Regimens containing RBV are more likely to cause anemia, shortness
 of breath, rash, itching, depression, irritability, and achy joints.



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ADVOCACY EXERCISE

Discussion Questions:

- 1. How can we increase access to HCV care and treatment?
- 2. What are the other services that we need, such as: peer support programs, better access to OST, supervised injection facilities, safe consumption spaces, and mental health programs?
- 3. Does your country have HCV treatment guidelines? Are they following the WHO treatment guidelines?

Action Steps:

- 1. What are our most important arguments for increasing access to HCV treatment to policy makers?
- 2. What are some of the problems with organizing stakeholders in your country or particular setting?
- 3. What strategies have been used to overcome these problems?
- 4. What are some initiatives to include the newer DAAs on national treatment lists?