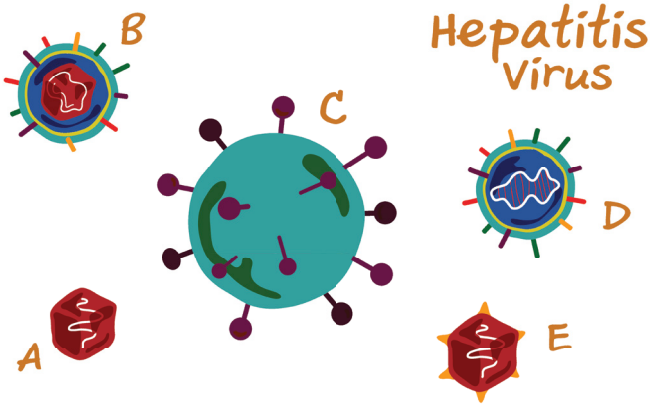
Fact Sheet on WHO Guidelines for the Screening, Care, and Treatment of Persons with Hepatitis C Infection



In April 2016, the World Health Organization (WHO) updated its guidelines on screening, care, and treatment of hepatitis C infection. The guidelines are aimed at helping policy makers and healthcare providers in low- and middle-income countries establish screening, care, and treatment programs for individuals infected with the virus. While the 2014 recommendations on screening and care remain unchanged, this updated version provides evidence-based recommendations for the treatment of hepatitis C using regimens containing only direct-acting antivirals (DAAs), where these medicines are available. This fact sheet summarizes the major recommendations.

The full guidelines can be accessed at http://who.int/hepatitis/publications/hepatitis-c-guidelines-2016/en/

WHAT DO THE GUIDELINES SAY?

Screening

Screening is the process that allows individuals to know if they have been infected with the hepatitis C virus. The guidelines recommend that:

- All individuals who have ever been part of a population with high rates of hepatitis C infection should be screened with the hepatitis C antibody test. This includes people who inject drugs (PWID) and people living with HIV (PLHIV).
- Anyone who has a positive antibody test should have a hepatitis C RNA test (also known as a hepatitis C viral load test) to confirm whether or not there is ongoing chronic infection.

Care

All people with chronic hepatitis C infection can take steps to prevent liver damage and should have access to appropriate medical care to monitor the condition of their livers.

- An alcohol intake assessment should be done for people who have confirmed hepatitis C infection, followed by an alcohol reduction intervention for those with moderate or high alcohol intake (more than nine glasses of beer or wine per week).
- PWID should be offered information on how to prevent acquisition of hepatitis B and C infection, including being offered vaccination against hepatitis B virus to avoid the risk of having two liver infections at the same time.
- Liver damage should be assessed using the APRI and FIB-4 scores, which are calculated using a combination of liver enzymes, platelets, and the person's age.[1] A special ultrasound of the liver that assesses liver stiffness (called a FibroScan®) can be used, if available.

[1] Online score calculators are available at: http://gihep.com/calculators/hepatology/fibrosis-4-score/ and http://www.hepatitisc.uw.edu/page/clinical-calculators/apri.

Treatment

People with chronic hepatitis C infection can receive medical treatment to cure their infection.

- DAA regimens should be used for the treatment of persons with hepatitis C infection rather than regimens with pegylated interferon/ribavirin.
- All adults and children with chronic hepatitis C infection should be evaluated for whether or not they are eligible to receive treatment.
  - ✔ HIV co-infection causes more rapid progression of hepatitis C disease; hepatitis C treatment should be considered for all co-infected individuals.
  - ✔ Stabilization of HIV disease with antiretroviral therapy is advisable prior to starting hepatitis C treatment.
  - ✔ Treating PWID for hepatitis C is efficacious and cost-effective, and it prevents transmission of hepatitis C.

The guidelines make the following recommendations about the preferred and alternative regimens used to treat hepatitis C, along with the durations of treatment.

Preferred regimens for persons without cirrhosis*

Genotype	Daclatasvir/ sofosbuvir	Ledipasvir/ sofosbuvir	Sofosbuvir/ ribavirin
Genotype 1	12 weeks	12 weeks	
Genotype 2			12 weeks
Genotype 3	12 weeks		24 weeks
Genotype 4	12 weeks	12 weeks	
Genotype 5		12 weeks	
Genotype 6		12 weeks	

**Treatment for both hepatitis C mono-infection and HIV/hepatitis C co-infection.*

Preferred regimens for persons with cirrhosis*

Genotype	Daclatasvir/ sofosbuvir	Daclatasvir/ sofosbuvir/ ribavirin	Ledipasvir/ sofosbuvir	Ledipasvir/ sofosbuvir/ ribavirin	Sofosbuvir/ ribavirin
Genotype 1	24 weeks	12 weeks	24 weeks	12 weeks	
Genotype 2					16 weeks
Genotype 3		24 weeks			
Genotype 4	24 weeks	12 weeks	24 weeks	12 weeks	
Genotype 5			24 weeks	12 weeks	
Genotype 6			24 weeks	12 weeks	

**Treatment for both hepatitis C mono-infection and HIV/hepatitis C co-infection.*

Alternative regimens for persons without cirrhosis

Genotype	Simeprevir/ sofosbuvir	Daclatasvir/ sofosbuvir	Ombitasvir/ paritaprevir/ ritonavir/ dasabuvir	Ombitasvir/ paritaprevir/ ritonavir/ ribavirin	Sofosbuvir/ pegylated interferon/ ribavirin
Genotype 1	12 weeks		12 weeks		
Genotype 2		12 weeks			
Genotype 3					
Genotype 4	12 weeks			12 weeks	
Genotype 5					12 weeks
Genotype 6					12 weeks

Alternative regimens for persons with cirrhosis

	For both compensated or decompensated cirrhosis	***These regimens should only be prescribed to persons with compensated cirrhosis, as they can cause liver failure and death when prescribed to persons with decompensated cirrhosis.***				
Genotype	**Daclatasvir/ sofosbuvir**	**Sofosbuvir/ pegylated interferon/ ribavirin**	**Simeprevir/ sofosbuvir**	**Simeprevir/ sofosbuvir/ ribavirin**	**Ombitasvir/ paritaprevir/ ritonavir/ dasabuvir**	**Ombitasvir/ paritaprevir/ ritonavir/ ribavirin**
Genotype 1			24 weeks	12 weeks	24 weeks	
Genotype 2	12 weeks					
Genotype 3		12 weeks				
Genotype 4			24 weeks	12 weeks		24 weeks
Genotype 5		12 weeks				
Genotype 6		12 weeks				

Monitoring for treatment response

Frequent monitoring of hepatitis C viral load is not required during treatment with DAAs. The guidelines suggest a simplified monitoring schedule.

Treatment week	**DAAs alone**			**DAAs + ribavirin**			**DAAs + pegylated interferon + ribavirin**			
	FBC, renal, liver function	Adherence, side effects	HCV RNA	FBC, renal, liver function	Adherence, side effects	HCV RNA	FBC, ALT, creatinine	Thyroid function	Adherence, side effects	HCV RNA
Baseline	X		X	X		X	X	X		X
Week 1				X	X		X		X	
Week 2				X	X		X		X	
Week 4	X	X		X	X		X		X	
Week 8				X	X		X		X	
Week 12				X	X		X	X	X	
Week 12 after end of treatment*			X	X		X	X	X		X
Week 24 after end of treatment										X

FBC: full blood count; HCV RNA: hepatitis C viral load; ALT: alanine aminotransferase

**After 12 weeks from the last day of treatment.*

Drug–drug interactions between HCV and HIV medicines*

Some HIV medicines can interact with the medicines used to treat hepatitis C. When these drug-drug interactions are anticipated, substitutions for HIV medications should be made before starting hepatitis C treatment.

HIV antiviral drugs	Daclatasvir	Ledipasvir/ sofosbuvir	Ombitasvir/ paritaprevir/ ritonavir	Ombitasvir/ paritaprevir/ ritonavir/ dasabuvir	Simeprevir	Sofosbuvir	Pegylated interferon	Ribavirin
Abacavir								
Emtricitabine								
Lamivudine								
Tenofovir								
Zidovudine								
Dolutegravir								
Efavirenz								
Nevirapine								
Lopinavir								
Ritonavir								

*Source: http://www.hep-druginteractions.org/

No clinically significant interaction expected

Potential interaction

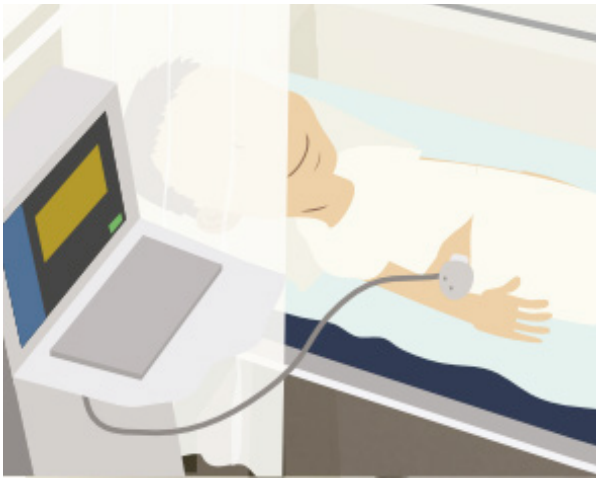
These drugs should not be co-administered

Regional relevance

The WHO's Regional Office for the Western Pacific (WPRO) has developed its Regional Action Plan for Viral Hepatitis, which has been validated by member states.[2] The WHO's Regional Office for South-East Asia (SEARO) is in the process of developing a similar strategy. Some national governments are also developing and finalizing their own strategies to address hepatitis C.

Less expensive, high-quality generic DAAs manufactured in the region are now available. While their availability is limited in some countries, generic companies are now working to complete regulatory requirements for registration of the medicines prior to future marketing and distribution. National regulatory bodies need to provide fast-track registration of DAAs to allow for broader treatment implementation.

The guidelines can be used by civil society, community organizations, and patient groups to advocate for access to testing, diagnostics, and treatment of hepatitis C. They also provide a framework for the establishment of national-level hepatitis C programs.



A patient with hepatitis C receives a FibroScan®.

[2] http://www.wpro.who.int/hepatitis/resource/features/regional_action_plan/en/

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