Comparing the Different Guidelines

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AASLD/IDSA

AASLD/IDSA HCV Guidance Introduction

Recommendations for Testing, Managing, and Treating Hepatitis C

"The landscape of treatment for hepatitis C virus (HCV) infection has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011"

"To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD) have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management"

The AASLD/IDSA guidelines were developed independently and without any funding from the pharmaceutical industry

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AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed September 25, 2014

AASLD/IDSA HCV Guidance Panel

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*Individual employees of the National Institutes of Health (NIH) have participated in the planning and development of the Guidance, although the NIH is not an official sponsor. The views expressed by the participants do not necessarily represent the opinions of the National Institutes of Health, the Department of Health and Human Services, or the United States Federal Government.

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Grading System for Recommendations

Classification	Description
Class I	Evidence and/or general agreement that a given diagnostic evaluation, procedure, or treatment is beneficial, useful, and effective
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness and efficacy of a diagnostic evaluation, procedure, or treatment
Class IIa	Weight of evidence and/or opinion is in favor of usefulness and efficacy
Class IIb	Usefulness and efficacy are less well established by evidence and/or opinion
Class III	Evidence and/or general agreement that a diagnostic evaluation, procedure, or treatment is not useful and effective or if it in some cases may be harmful

Level of Evidence	Description
Level A	Data derived from multiple randomized clinical trials or meta-analyses
Level B	Data derived from a single randomized trial, or nonrandomized studies
Level C	Consensus opinion of experts, case studies, or standard of care

Adapted from the American College of Cardiology and the American Heart Association Practice Guidelines. American Heart Association. http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/documents/downloadable/ucm-319826.p4. Accessed on January 27, 2014.
Shiffman RN, et al. Ann Intern Med. 2003;139(6):493-498.

AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed September 25, 2014

AASLD/IDSA Guidance Update:

- The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences by the achievement of virologic cure
- There are numerous benefits of achieving SVR including decreased liver inflammation, fibrosis/cirrhosis, clinical sequelae of portal hypertension, risk in HCC, liver transplantation, and symptoms/mortality from severe extrahepatic manifestations. Lastly, SVR is associated with substantially improving quality of life.
- Initiation of therapy should be prioritized first to those specific populations that will derive the most benefit or have the greatest impact on further HCV transmission

Patients with advanced fibrosis (F3) or compensated cirrhosis (F4)	Liver transplant recipients	Severe extrahepatic manifestations of HCV (cryoglobulinemia, proteinuria, N-H lymphoma, DM)	High-risk groups: MSM with high-risk sexual practices, IDU, incarcerated persons, hemodialysis

- Other populations at high risk for liver disease progression (F2) or with extrahepatic manifestations should be given priority for therapy in an effort to decrease the risk of clinical consequences

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Highest Priority for Treatment Owing to Highest Risk for Severe Complications

Complication	Rating
Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4)	Class I, Level A
Organ transplant	Class I, Level B
Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (eg, vasculitis)	Class I, Level B
Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis	Class IIa, Level B

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High Priority for Treatment Owing to High Risk for Complications

Complication	Rating
Fibrosis (Metavir F2)	Class I, Level B
HIV-1 coinfection	Class I, Level B
HBV coinfection	Class IIa, Level C
Other coexistent liver disease (eg, NASH)	Class IIa, Level C
Debilitating fatigue	Class IIa, Level B
Type 2 Diabetes mellitus (insulin resistant)	Class IIa, Level B
Porphyria cutanea tarda	Class IIb, Level C

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FDA Approved SOF Regimens and AASLD/IDSA Guidance

Genotype	Patient Characteristics		Regimen	AASLD/IDSA Recommended	AASLD/IDSA Alternative
GT1 GT4	Treatment-Naïve & Prior PegIFN + RBV Relapser (± compensated cirrhosis)	IFN-Eligible	SOF + PegIFN + RBV x12 weeks (regardless of subtype)	✓	
		IFN-Ineligible (GT 1 only)	SOF + RBV x24 weeks (regardless of subtype)		✓
	Prior PegIFN + RBV Failure*		SOF + PegIFN + RBV x12 weeks		✓
GT2	Treatment-Naïve & Prior PegIFN + RBV Relapser (± compensated cirrhosis)		SOF + RBV x12 weeks	✓	
	Prior PegIFN + RBV Failure*		SOF + RBV x12 weeks	✓	
GT3	Treatment-Naïve & Prior PegIFN + RBV Relapser (± compensated cirrhosis)		SOF + RBV x24 weeks	✓	
	Prior PegIFN + RBV Failure*		SOF + RBV x24 weeks	✓	

*Nonresponder is defined as partial or null response to treatment with PegIFN + RBV. Relapse to prior therapy should be treated the same as treatment-naïve.

AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed September 25, 2014
SOVALDI US PI. Gilead Sciences, Inc. December 2013.

Guidance Document Language

- "This section *assumes that a decision to treat has been made* and provides guidance regarding optimal treatment."
- "In many instances, however, *it may be advisable to delay treatment for some patients with documented early fibrosis stage (F0-F2),* because waiting for future highly effective, pangenotypic, DAA combinations in IFN-free regimens may be prudent."

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AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed August 12, 2014.

When and in Whom to Initiate HCV Therapy

- Treatment is recommended for patients with chronic HCV infection (Class I, Level A)
  - Treatment is assigned the highest priority for those patients with advanced fibrosis (METAVIR F3), those with compensated cirrhosis (METAVIR F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C.
  - Based on available resources, treatment should be prioritized as necessary so that patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications are given high priority.

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AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed August 12, 2014.

GT 1 Treatment Naïve (or Prior Relapse) Patients: Recommended Regimens

- Eligible To Receive IFN
  - SOF + PEG/RBV for 12 weeks
- Not Eligible To Receive IFN
  - SOF + SMV ± RBV for 12 weeks (not FDA approved)
  - Should be considered ONLY in those patients who require immediate treatment

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AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed August 12, 2014.

GT 1 Treatment Naïve (or Prior Relapse) Patients: Alternative Regimens

- Eligible To Receive IFN
  - SMV + PEG/RBV for 12 weeks followed by PEG/RBV for an additional 12 weeks
  - Only in
    - GT 1b patients
    - GT 1a patients in whom Q80K polymorphism is not detected prior to treatment

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AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed August 12, 2014.

GT 1 Treatment Naïve (or Prior Relapse) Patients: Alternative Regimens

- Not Eligible To Receive IFN
  - SOF + RBV for 24 weeks
  - Preliminary data suggest that this regimen may be less effective than daily SOF plus SMV, particularly among patients with cirrhosis
  - Should be considered ONLY in those patients who require immediate treatment

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AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed August 12, 2014.

GT 1 Previous Nonresponders: Recommended Regimens

- Previously failed PEG/RBV
  - SOF + SMV ± RBV for 12 weeks
- Previously failed PEG/RBV + Protease Inhibitor
  - SOF + PEG/RBV for 12 weeks followed by PEG/RBV for up to an additional 12 weeks

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GT 1 Previous Nonresponders: Alternative Regimens

- GT 1 previous PEG/RBV (with or without protease inhibitor) nonresponders
  - Eligible to Receive IFN: SOF + PEG/RBV for 12 weeks followed by PEG/RBV for up to an additional 12 weeks
  - Ineligible to Receive IFN: SOF + RBV for 24 weeks
- GT 1 previous PEG/RBV (without protease inhibitor) nonresponders
  - Eligible to Receive IFN: SMV + PEG/RBV for 12 weeks followed by PEG/RBV for an additional 36 weeks (48 week total duration)

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AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed August 12, 2014.

AASLD/IDSA Guidance Document Recommendations For GT 2 and GT 3 Patients

AASLD/IDSA Guidance Document on GT 2 and GT 3 Patients

- GT 2
  - Treatment Naïve
    - SOF + RBV for 12 weeks
  - Treatment Experienced
    - SOF + RBV for 12 weeks (patients with cirrhosis may benefit by extension to 16 weeks)
    - SOF + PEG/RBV for 12 weeks (alternative)
- GT 3
  - Treatment Naïve and Treatment Experienced
    - SOF + RBV for 24 weeks (recommended)
    - SOF + PEG/RBV for 12 weeks (alternative)

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AASLD/IDSA Guidance Document Recommendations For Pre- and Post-Transplant Patients

AASLD/IDSA Guidance Document on Decompensated Cirrhosis

- The recommended regimen for patients with any HCV genotype who have decompensated cirrhosis (moderate or severe hepatic impairment; CTP class B or C) who may or may not be candidates for liver transplantation, including those with HCC. This regimen should be used only by highly experienced HCV providers.
  - SOF + RBV (with consideration of the patient's creatinine clearance and hemoglobin level) for up to 48 weeks

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Guidance for GT 1 in Allograft Liver, Including Those With Compensated Cirrhosis

- Recommended
  - SOF + SMV +/- RBV for 12-24 weeks*
- Alternate
  - SOF + RBV (consider patients CrCl value and hemoglobin level) +/- PEG (in the absence of contraindication to its use) for 24 weeks

*SMV/SOF has not been studied in the post-transplant setting; however, DDI studies in non-infected participants indicate SMV can be dosed safely in conjunction with calcineurin inhibitors

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Guidance for GT 2 or GT 3 in Allograft Liver

- Treatment naive with GT 2 or GT 3 in the allograft liver, including those with compensated cirrhosis
  - SOF + RBV (consider patients CrCl value and hemoglobin level) for 24 weeks

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AASLD/IDSA Guidance Document Recommendations For HCV/HIV Coinfected Patients

Guidance for HCV/HIV Coinfection in GT 1 Patients (Same as HCV Monoinfection)

- Treatment-naïve or prior relapsers
  - IFN eligible
    - SOF + PEG/RBV for 12 weeks
  - IFN ineligible
    - SOF + RBV for 24 weeks
    - SOF + SMV ± RBV for 12 weeks
- Treatment-experienced
  - Previously failed PEG/RBV
    - SOF + SMV ± RBV for 12 weeks
  - Previously failed PEG/RBV + Protease Inhibitor
    - SOF + PEG/RBV for 12 weeks followed by PEG/RBV for up to an additional 12 weeks

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Guidance for HCV/HIV Coinfection in GT 2, GT 3, GT 4, GT 5 and GT 6

- GT 2, 5 and 6 regardless of treatment history
  - SOF + RBV for 12 weeks
- GT 3 regardless of treatment history
  - SOF + RBV for 24 weeks
- GT 4
  - SOF + PEG/RBV for 12 weeks (IFN eligible)
  - SOF + RBV for 24 weeks (IFN ineligible)

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World Health Organization

WHO Guidelines

- Prioritise treatment for METAVIR F3–F4, if resources permit consider treating F1 and F2
- Treating both infections is a priority for persons with HIV/HCV co-infection
- Treatment of PWIDs is cost-effective. The higher the treatment rate, the more cost-effective HCV case-finding becomes – resulting in a greater population impact
- New compounds can cure >90% of persons with HCV infection and are effective against genotypes that were previously difficult to treat
- SOF + RBV ± PegIFN is recommended in GT 1, 2, 3 and 4 HCV infection rather than PegIFN + RBV alone
- The efficacy of SOF with RBV alone or PegIFN + RBV resulted in much higher SVR rates and a low rate of SOF-associated adverse events

GT	Recommendation
1–4	SOF + RBV ± PegIFN preferred vs PegIFN + RBV [Strong recommendation, high quality of evidence]
1a (no Q80K) or 1b	SMV + PegIFN + RBV preferred vs PegIFN + RBV [Strong recommendation, high quality of evidence]
1	BOC or TVR + PegIFN + RBV preferred vs PegIFN + RBV [Conditional recommendation, moderate high quality of evidence]

BOC: boceprevir; GT: genotype; PegIFN: pegylated interferon; PWIDs: people who inject drugs; RBV: ribavirin; SMV: simeprevir; SOF: sofosbuvir; TVR: telaprevir

World Health Organization Guidelines for HCV. Available at: http://www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/. Accessed June 2014

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WHO Guidelines Recommended SOF-Based Regimens

GT	Recommendation	IFN-ineligible
1	SOF + PegIFN + RBV (12 w)	SOF + RBV (24 w)
2	SOF + RBV (12 w)	
3	SOF + RBV (24 w) SOF + PegIFN + RBV (12 w)	
4	SOF + PegIFN + RBV (12 w)	

GT: genotype; IFN; interferon; PegIFN: pegylated interferon; RBV: ribavirin; SOF: sofosbuvir; w: week

World Health Organization Guidelines for HCV. Available at: http://www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/. Accessed June 2014

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EASL

EASL Recommendations

- All TN and TE-patients with compensated disease should be considered for therapy
  - Prioritise F3–F4; treatment justified in F2; indication for/timing of therapy individualised for F0–F1
  - IFN-free (ideally RBV-free therapy) should be considered for patients with decompensated cirrhosis on the transplant list
- A SOF-containing regimen for 12 weeks is the 1st option listed for all genotypes:
  - GT 1, 3, 4, 5 & 6 (SOF + PegIFN + RBV for 12 weeks)
  - GT 2 (all-oral SOF + RBV for 12 weeks)
- Indications for HCV treatment in HCV/HIV co-infected persons are identical to those with HCV mono-infection

DCV: daclatasvir; GT: genotype; IFN: interferon;
PegIFN: pegylated interferon; RBV: ribavirin; SMV: simeprevir; SOF: sofosbuvir;
TE: treatment-experienced; TN: treatment-naive

EASL Recommendations on Treatment of Hepatitis C 2014. Available at: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C.pdf. Accessed June 2014.

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EASL Recommendations: Main Recommendations

GT	Population	Highest graded recommendations	IFN-ineligible
1	TN/TE	SOF + PegIFN + RBV (12 w) [A1]	SOF + RBV (24 w) [B2]
2	TN/TE TE cirrhotic	SOF + RBV (12 w) [A1] SOF + RBV (16 or 20 w) [B1]	
3	TN/TE TN	SOF + PegIFN + RBV (12 w) [A2] SOF + RBV (24 w) [A2]	
4	TN/TE TN/TE relapser TE partial/null TN/TE	SOF + PegIFN + RBV (12 w) [B1] SMV (12 w) + PegIFN + RBV (24 w) [B1] SMV (12 w) + PegIFN + RBV (48 w) [B1] DCV + PegIFN + RBV (24 w) [B1]	SOF + RBV (24 w) [C2]
5 or 6	TN/TE	SOF + PegIFN + RBV (12 w) [B1]	SOF + RBV (24 w) [C2]

DCV: daclatasvir; GT: genotype; IFN: interferon; PegIFN: pegylated interferon; RBV: ribavirin; SMV: simeprevir; SOF: sofosbuvir; TE: treatment-experienced; TN: treatment-naïve; w: week

EASL Recommendations on Treatment of Hepatitis C 2014. Available at: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C.pdf. Accessed June 2014

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EASL Recommendations: 1st listed and Alternatives

GT	Population	1st listed treatment option	Alternative options	IFN-ineligible
1	TN/TE	SOF + PegIFN + RBV (12 w) [A1]	SMV (12 w) + PegIFN + RBV (24 w) [B1]* TE partial/null: SMV (12 w) + PegIFN + RBV (48 w) [B1]* DCV + PegIFN + RBV (24 w) [B1]** SOF + SMV (± RBV)† (12 w) [B1] TN: SOF + DCV (± RBV)† (12 w) [B1] TE: SOF + DCV (± RBV)† (24 w) [B1]	SOF + RBV (24 w) [B2]
2	TN/TE TE cirrhotic	SOF + RBV (12 w) [A1] SOF + RBV (16 or 20 w) [B1]	SOF + PegIFN + RBV (12 w) [B1]	
3	TN/TE TN	SOF + PegIFN + RBV (12 w) [A2] SOF + RBV (24 w) [A2]	TN: SOF + DCV (± RBV)† (12 w) [B1] TE: SOF + DCV (± RBV)† (24 w) [B1]	
4	TN/TE	SOF + PegIFN + RBV (12 w) [B1]	TN/relapsers: SMV (12 w) + PegIFN + RBV (24) [B1] TE partial/null: SMV (12 w) + PegIFN + RBV (48 w) [B1] DCV + PegIFN + RBV (24 w) [B1] SOF + SMV (± RBV)† (12 w) [B2] TN: SOF + DCV (± RBV)† (12 w) [B2] TE: SOF + DCV (± RBV)† (24 w) [B2]	SOF + RBV (24 w) [C2]
5 or 6	TN/TE	SOF + PegIFN + RBV (12 w) [B1]		SOF + RBV (24 w) [C2]

*Not to be used in patients with GT 1a Q80K at baseline; ** Not to be used in GT 1a; †Preliminary results indicate no major advantage of adding RBV. However, this should be considered in patients with poor predictors of response to therapy, especially prior non-responders and/or patients with cirrhosis

DCV: daclatasvir; GT: genotype; IFN: interferon; PegIFN + RBV: pegylated interferon/ribavirin; RBV: ribavirin; SMV: simeprevir; SOF: sofosbuvir; TE: treatment-experienced; TN: treatment-naïve; w: week

EASL Recommendations on Treatment of Hepatitis C 2014. Available at: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C.pdf. Accessed June 2014

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EASL Recommendations: Special Populations

Group	Treatment
Compensated cirrhosis	▪ Patients with compensated cirrhosis should be treated, in the absence of contraindications, in order to prevent short- to mid-term complications ▪ IFN-free combination regimens are preferred ▪ If a 12-24 week IFN-based DAA regimen is considered tolerable in patients with compensated cirrhosis and good liver function and without cytopenia, these patients can be treated as recommended above across genotypes ▪ Patients with cirrhosis should undergo regular surveillance for HCC, irrespective of SVR
Indications for liver transplant	▪ Antiviral therapy is indicated because it prevents graft infection ▪ Patients with conserved liver function (Child-Pugh A) in whom the indication for transplantation is HCC should be treated with SOF + RBV until liver transplantation. Alternative options: SOF + PegIFN + RBV (12 w) or SOF + DCV + RBV (12 w) prior to transplantation ▪ Patients with decompensated cirrhosis awaiting liver transplantation (Child-Pugh B and C) can be treated with SOF + RBV until liver transplantation in experienced centers under close monitoring. IFN is contraindicated. Alternative option: SOF + DCV + RBV until liver transplantation
Post-liver transplant recurrence	▪ Patients with post-transplant recurrence of HCV infection should be considered for therapy. Significant fibrosis or portal hypertension one year after transplantation predict rapid disease progression and graft loss, and indicate more urgent antiviral treatment ▪ GT 2: SOF + RBV (12 to 24 w) ▪ GT 1, 3, 4, 5 or 6: SOF + DCV ± RBV (12 to 24 w) ▪ GT 1 or 4: SOF + SMV ± RBV (12 to 24 w) ▪ No dose adjustment is required for tacrolimus or cyclosporine with any of these combinations. Careful monitoring is important in the absence of safety data in this population

DAA; direct-acting antiviral agent; DCV: daclatasvir;
GT: genotype; HCC: hepatocellular carcinoma; IFN: interferon;
PegIFN + RBV: pegylated interferon/ribavirin; RBV: ribavirin;
SMV: simeprevir; SOF: sofosbuvir;
SVR: sustained virological response; w: week

EASL Recommendations on Treatment of Hepatitis C 2014. Available at: http://files.easl.eu/easl-recommendations-on-treatment-of-hepatitis-C.pdf. Accessed June 2014.

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Summary

- Multiple guidelines/guidance documents
  - Relevant to financial status of healthcare systems
  - Drug availability
  - Subject to change over time
- Not feasible to have one standard across all countries
- Common Goal
  - Eradicate HCV (will be slow process)
  - Treat those in greatest need

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