THE “ABC”S OF VIRAL HEPATITIS 2019

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Objectives

1. Discuss current treatments for hepatitis C and the importance of post-cure follow up for certain patients
2. Review updated treatment guidelines for hepatitis B, with a focus on recommended agents
3. Briefly outline the current hepatitis A outbreak in the US and updated ACIP recommendations for vaccination of vulnerable populations

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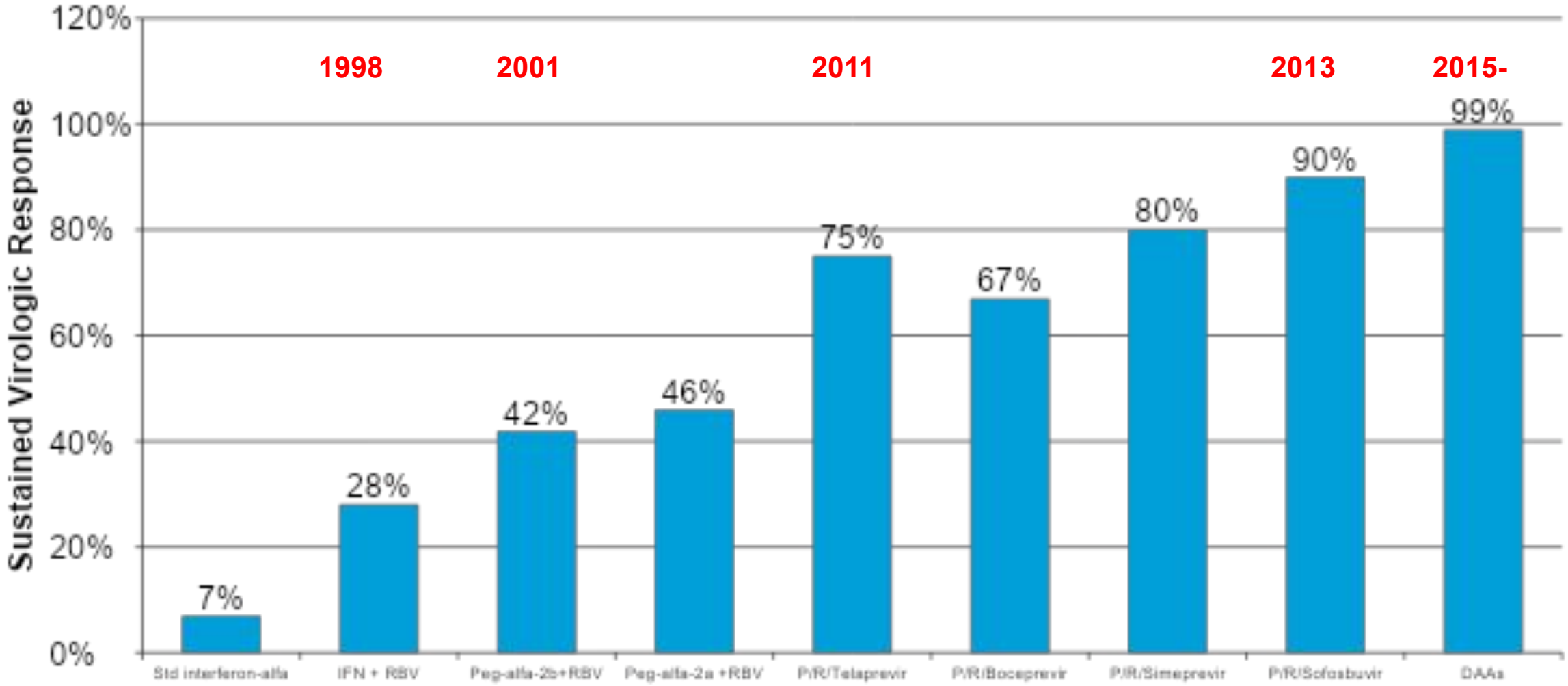
Evolution of HCV Therapy: Naïve Genotype 1 Patients



McHutchison, NEJM 1998; 339: 1485-92
Fried, NEJM 2002; 347: 975-82
Manns, Lancet 2001; 358:958-65
Lawitz, NEJM 2013
Jacobson, NEJM 2011; 364:2405-16
Poordad, NEJM 2011; 364: 1195-206
Jacobson, AASLD 2013 #1122

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Currently Approved DAA Regimens

PROTEASE	POLYMERASE	NS5A INHIBITOR	TRADE NAME	APPROVAL DATE
Simeprevir	Sofosbuvir			11/6/14
	Sofosbuvir	Ledipasvir	Harvoni	10/10/14
Paritaprevir/ritonavir	Dasabuvir	Ombitasvir	Viekira Pak	12/19/14
	Sofosbuvir (Sovaldi)	Daclatasvir (Daklinza)		7/24/15
Paritaprevir/ritonavir		Ombitasvir	Technivie	7/24/16
Grazoprevir		Elbasvir	Zepatier	1/24/16
	Sofosbuvir	Velpatasvir	Epclusa	6/28/16
Voxilaprevir	Sofosbuvir	Velpatasvir	Vosevi	7/18/17
Glecaprevir		Pibrentasvir	Mavyret	8/3/17

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Sofosbuvir/Ledipasvir (Harvoni)

Dosing	400-90 mg once daily with or without food
Duration	8-24 weeks
Drug Interactions*	AMIODARONE, St. John's wort, rifampin, anticonvulsants, rosuvastatin Acid reducers: Antacids, H2-blockers, PPIs
Adverse Effects	Fatigue, headache, asthenia
Renal	Not recommended in CrCl<30 or ESRD
Liver	Can be used in Child A, B, C cirrhosis +/- decompensation Can be used in liver transplant
Special Considerations	May be used with ribavirin in treatment-experienced or decompensated cirrhosis 8 week duration an option for GT1 naïve patients with no cirrhosis and baseline viral load <6,000,000 IU/mL Available as an Authorized Generic

*not all drug interactions are listed here

1	2	3	4	5	6
✓			✓	✓	✓

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Paritaprevir/ritonavir + ombitasvir + dasabuvir (Viekira XR)

Dosing	3 fixed-dose tablets once daily with food
Duration	12-24 weeks
Drug Interactions*	CYP3A; anticonvulsants; gemfibrozil, rifampin, OCPs with EE, St Johns wort, atorvastatin/lovastatin/simvastatin
Adverse Effects	Fatigue, nausea, pruritus, insomnia, asthenia
Renal	No dosage adjustment including dialysis
Liver	Contraindicated in moderate to severe hepatic impairment (Child B, C) OK in liver transplant if no hepatic impairment
Special Considerations	Must be used with ribavirin for genotype 1a 1% experience elevation of ALT to >5x ULN in first 4 weeks

*not all drug interactions are listed here

1	2	3	4	5	6
✓					

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Grazoprevir-Elbasvir (Zepatier)

Dosing	100/50 mg fixed-dose combination once daily with or without food
Duration	12-16 weeks
Drug Interactions*	OATP1B1/3 inhibitors, P450 3A inducers Phenytoin, carbamazepine, rifampin, St Johns wort, cyclosporine
Adverse Effects	Fatigue, headache, nausea
Renal	No dosage adjustment needed, including dialysis
Liver	Contraindicated in moderate-severe hepatic impairment (Child B or C cirrhosis) Safety not established in liver transplant
Special Considerations	Must test for NS5a resistance-associated substitutions (RAS) prior to use in GT1a; if present, add ribavirin and extend to 16 weeks Monitor ALT at week 8 and 12

*not all drug interactions are listed here

1	2	3	4	5	6
✓			✓		

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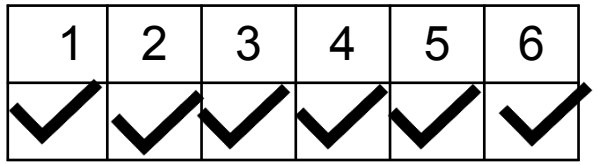
Sofosbuvir-Velpatasvir (Epclusa)

Dosing	400-100 mg fixed-dose tablet once daily with or without food
Duration	12 weeks
Drug Interactions*	AMIODARONE, rifampin, St Johns wort, carbamazepine, phenytoin, rosuvastatin, atorvastatin Acid Reducing Agents: do not administer with PPIs
Adverse Effects	Headache, fatigue
Renal	Not recommended in CrCl<30 or ESRD
Liver	Can be used in Child A, B, C cirrhosis +/- decompensation
Special Considerations	Use with ribavirin in decompensated cirrhosis Available as an Authorized Generic (AG)

*not all drug interactions are listed here



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Sofosbuvir-Velpatasvir- Voxilaprevir (Vosevi)

Dosing	400-100-100 mg fixed-dose tablet once daily with food
Duration	12 weeks
Drug Interactions*	AMIODARONE, rifampin, St Johns wort, carbamazepine, phenytoin, rosuvastatin, pitavastatin, dabigatran, cyclosporine Acid Reducing Agents
Adverse Effects	Headache, fatigue, diarrhea, nausea
Renal	Not recommended in CrCl<30 or ESRD
Liver	Contraindicated in moderate-severe hepatic impairment (Child B or C cirrhosis)
Special Considerations	Indicated in patients failing a prior regimen containing SOF and NS5a inhibitor or GT1a/3 failing prior SOF regimen without NS5a inhibitor

*not all drug interactions are listed here

1	2	3	4	5	6
✓	✓	✓	✓	✓	✓

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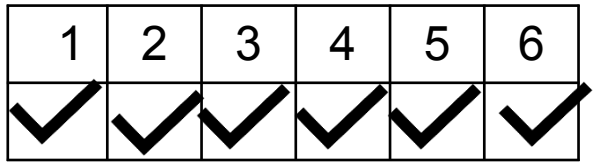
Glecaprevir-Pibrentasvir (Mavyret)

Dosing	Three 100-40 mg fixed-dose tablets once daily with food
Duration	8-16 weeks
Drug Interactions*	Rifampin, carbamazepine, St Johns wort, OCPs with EE Statins; cyclosporine if dose >100 mg per day
Adverse Effects	Headache, fatigue
Renal	No dosage adjustment, including dialysis
Liver	Not recommended in Child B cirrhosis, contraindicated in Child C OK in liver transplant as long as hepatic function acceptable
Special Considerations	Has been studied in DAA treatment-experienced patients who received either an NS5a OR NS3/4A. Patients with treatment-experience to both had high failure rates and emergence of drug resistance

*not all drug interactions are listed here



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Can I use this HIV drug with this HCV drug?

	Sofosbuvir-Ledipasvir	Sofosbuvir-Velpatasvir	Elbasvir-Grazoprevir	PrOD	Sof-Vel-Vox	Glecaprevir-Pibrentasvir
Efavirenz	Maybe - caution	No	No	No	No	No
Complera	Yes	Yes	Yes	Yes	Yes	Yes
Odefsey	Yes	Yes	Yes	Yes	Yes	Yes
Stribild	Maybe - caution	Maybe – caution	No	No	Maybe - caution	Yes
Genvoya	Yes	Yes	No	No	Yes	Yes
Biktarvy	Yes	Yes	Yes	Yes	Yes	Yes
Juluca	Yes	Yes	Yes	Yes		Yes
Doravirine	Yes	Yes	Yes	Yes	Yes	Yes
Darunavir	Yes	Yes	No	No	Yes (if QD)	No
Atazanavir	Yes	Yes	No	No	No	No
Dolutegravir	Yes	Yes	Yes	Yes	Yes	Yes

http://hep-druginteractions.org

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Black Box Warning: Hepatitis B Reactivation

All DAAs now carry a black box warning regarding risk of hepatitis B reactivation while on treatment

All patients should be screened for hepatitis B, including sAg and anti-HBc prior to starting Hep C treatment

29 cases of reactivation reported to FDA 2013-2016, 2 have been fatal, 1 liver transplant

Bersoff-Matcha, Ann Int Med 2017; 166: 792-98

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Choosing a Regimen and Duration: Things to Consider

- Genotype
- **Presence [illegible]ce of cirrhosis (compensated, decompensated)**
- Past treatme[illegible]
- Concomitant medica[illegible]teractions
- Whether 8 weeks is an opti[illegible]r/ledipasvir, glecaprevir/pibrentasvir)
- Kidney function (PrOD, GRZ-ELB, [illegible]ferred)
- Whether ribavirin would need to be includ[illegible]y to avoid)
- Need for additional testing (NS5A RAS with GRZ[illegible]1a)

INSURANCE PREFERENCE!!!

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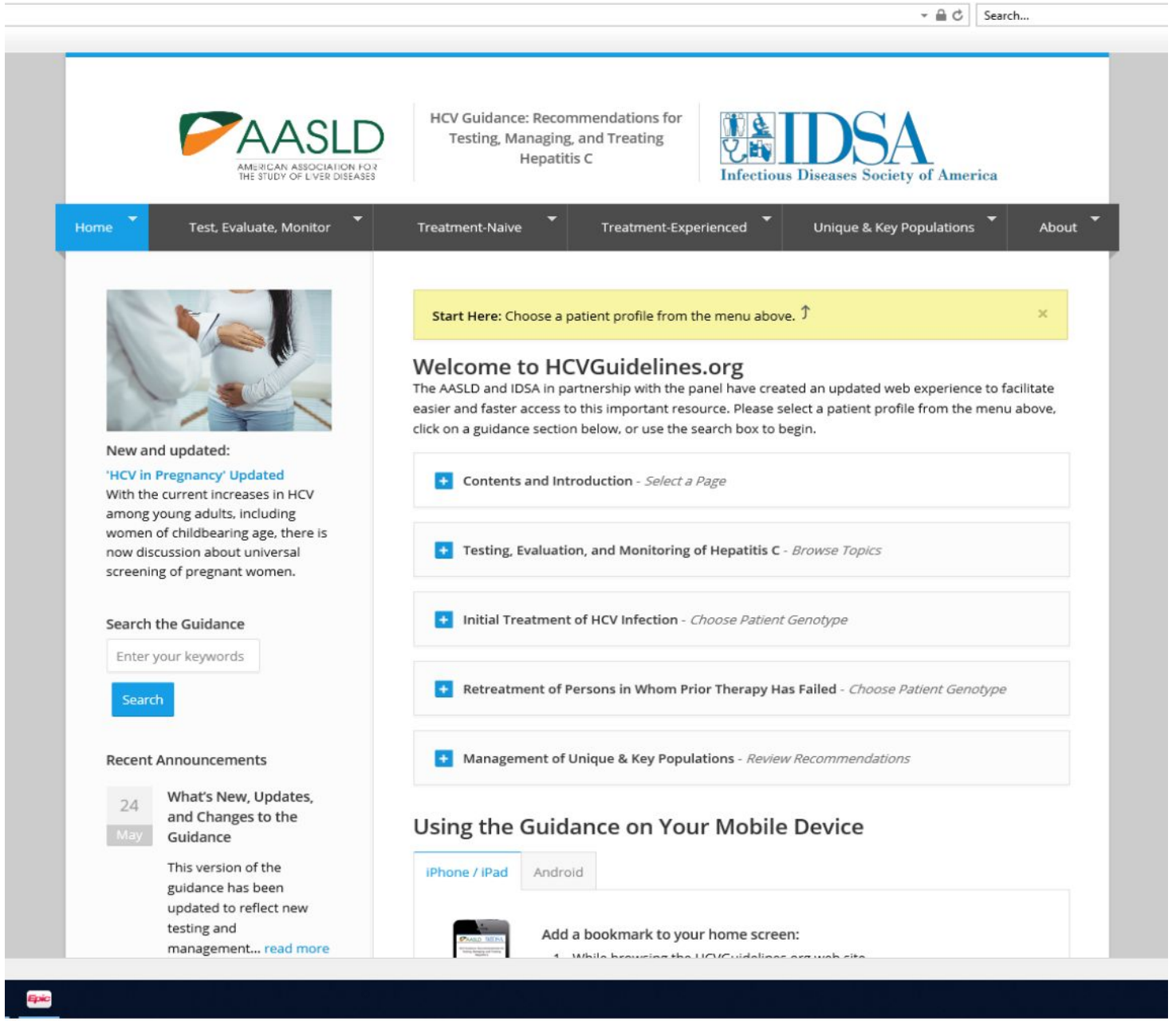
www.hcvguidelines.org



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AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

Testing, Managing, and Treating Hepatitis C

IDSA
Infectious Diseases Society of America

New and updated:

'HCV in Pregnancy' Updated

With the current increases in HCV among young adults, including women of childbearing age, there is now discussion about universal screening of pregnant women.

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- **Contents and Introduction** - *Select a Page*
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- **Retreatment of Persons in Whom Prior Therapy Has Failed** - *Choose Patient Genotype*

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HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

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Recommendations and Evidence
Summary of Recommendations

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Slides: This Section

Help Topics

Abbreviations

Section Contents

- Retreatment Introduction

NS3 Protease Inhibitor + Peginterferon/Ribavirin-Experienced, Genotype 1 Patients Without Cirrhosis

Recommended and alternative regimens listed by evidence level and alphabetically for:

NS3 Protease Inhibitor (Telaprevir, Boceprevir, or Simeprevir) + Peginterferon/Ribavirin-Experienced, Genotype 1 Patients Without Cirrhosis

RECOMMENDED	DURATION	RATING
Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg)	12 weeks	I, A
Daily fixed-dose combination of sofosbuvir (400 mg)/velpatasvir (100 mg)	12 weeks	I, A
Daily fixed-dose combination of glecaprevir (300 mg)/pibrentasvir (120 mg)[a]	12 weeks	IIa, B
ALTERNATIVE	**DURATION**	**RATING**
Daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100 mg) plus weight-based ribavirin for all genotype 1b patients, and genotype 1a patients without baseline NS5A RASs[b] for elbasvir	12 weeks	IIa, B
Daily fixed-dose combination of elbasvir (50 mg)/grazoprevir (100 mg) plus weight-based ribavirin for genotype 1a patients with baseline NS5A RASs[b] for elbasvir	16 weeks	IIa, B

[a] This is a 3-tablet coformulation. Please refer to the prescribing information.

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Help Topics

Abbreviations

Management of Unique & Key Popu tion

The following pages include guidance for management of pa populations.

- Patients With HIV/HCV Coinfection
- Patients With Decompensated Cirrhosis
- Patients Who Develop Recurrent HCV Infection Post Liver
- Patients With Renal Impairment
- Kidney Transplant Patients
- Management of Acute HCV Infection
- HCV in Pregnancy
- HCV in Children

Post-Treatment Monitoring of Patients who Achieve Cure

American Gastroenterological Association Institute Clinical Practice Update—Expert Review: Care of Patients Who Have Achieved a Sustained Virologic Response After Antiviral Therapy for Chronic Hepatitis C Infection

Ira M. Jacobson,[1] Joseph K. Lim,[2] and Michael W. Fried[3]

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HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA
Infectious Diseases Society of America

Jacobson, Gastroenterology 2017; 152:1578-87
AASLD/IDSA HCV Guidelines
www.hcvguidelines.org

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Post-treatment viral load testing

1. Sustained virologic response (SVR = cure) should be confirmed by undetectable HCV RNA 12 weeks after completion of therapy
2. Routine confirmation of SVR at week 48 post-treatment is recommended
3. Routine testing for HCV RNA beyond week 48 is NOT recommended

Jacobson, Gastroenterology 2017; 152:1578-87
AASLD/IDSA HCV Guidelines
www.hcvguidelines.org

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Durability of SVR: late relapses are uncommon

Study	N	Regimen	Relapse Rate
Zeuzem, AASLD 2015, Abs 1086	1054	PrOD*	4/1054 (0.5%)
Sarrazin, CID 2017; 64:44-52	3004	Sofosbuvir-based	5/3004 (0.2%)
Schwabe, AASLD 2018, Abs 595	6607	Sofosbuvir-based	8/6607 (0.1%)

*Paritеprevir/ritonavir + ombitasvir + dasabuvir

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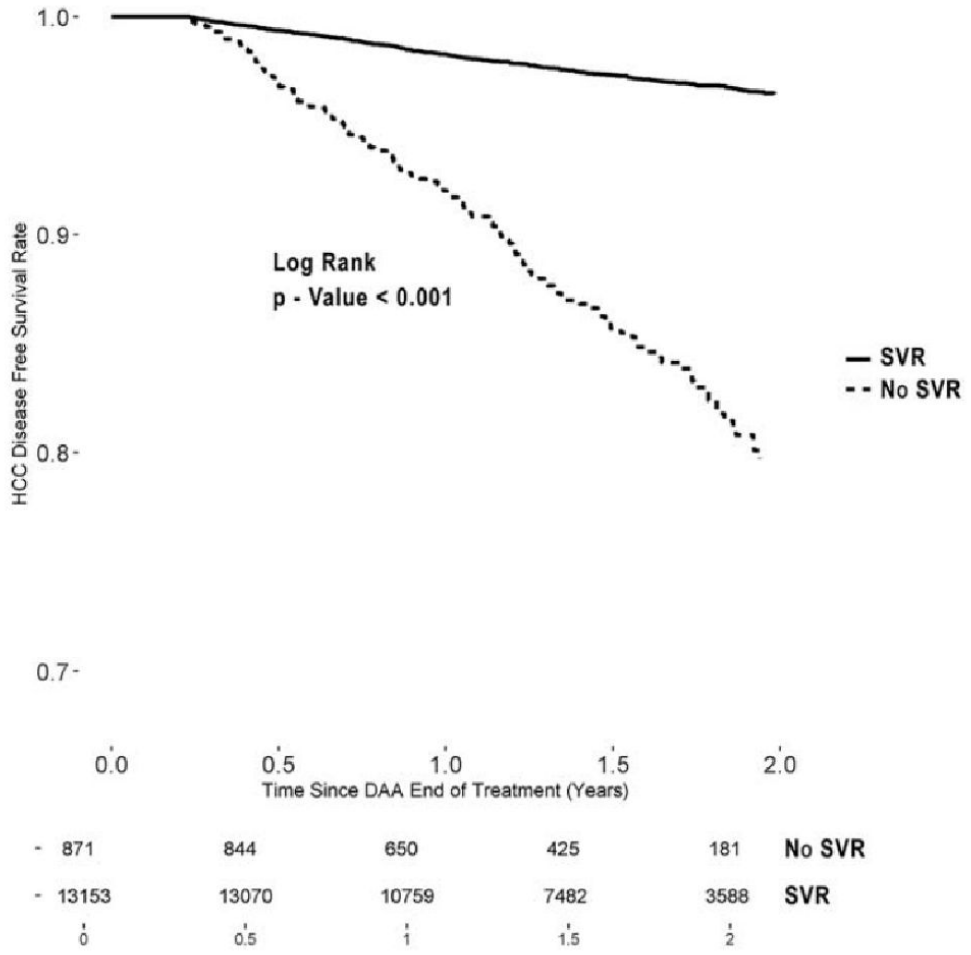
Risk of HCC after SVR

In patients who had advanced liver disease prior to treatment, risk of HCC decreased by 83.5%

HCC still occurred in those who had SVR



Backus, Hepatology 2019; 69: 487-497

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HCC: Advanced Liver Disease

	No SVR		SVR		HCC reduction	
	HCC	HCC/100 patient-years	HCC	HCC/100 patient-years	Reduction	*P*
Total	140	11.5 (8.6-13.8)	397	1.9 (1.7-2.1)	83.5%	<0.001
	1-Year HCC Rate					
Total	9.4% (7.4-11.9%)		1.9% (1.7%-2.2%)		79.8%	<0.001

Backus, Hepatology 2019; 69: 487-497

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Risk of HCC after SVR

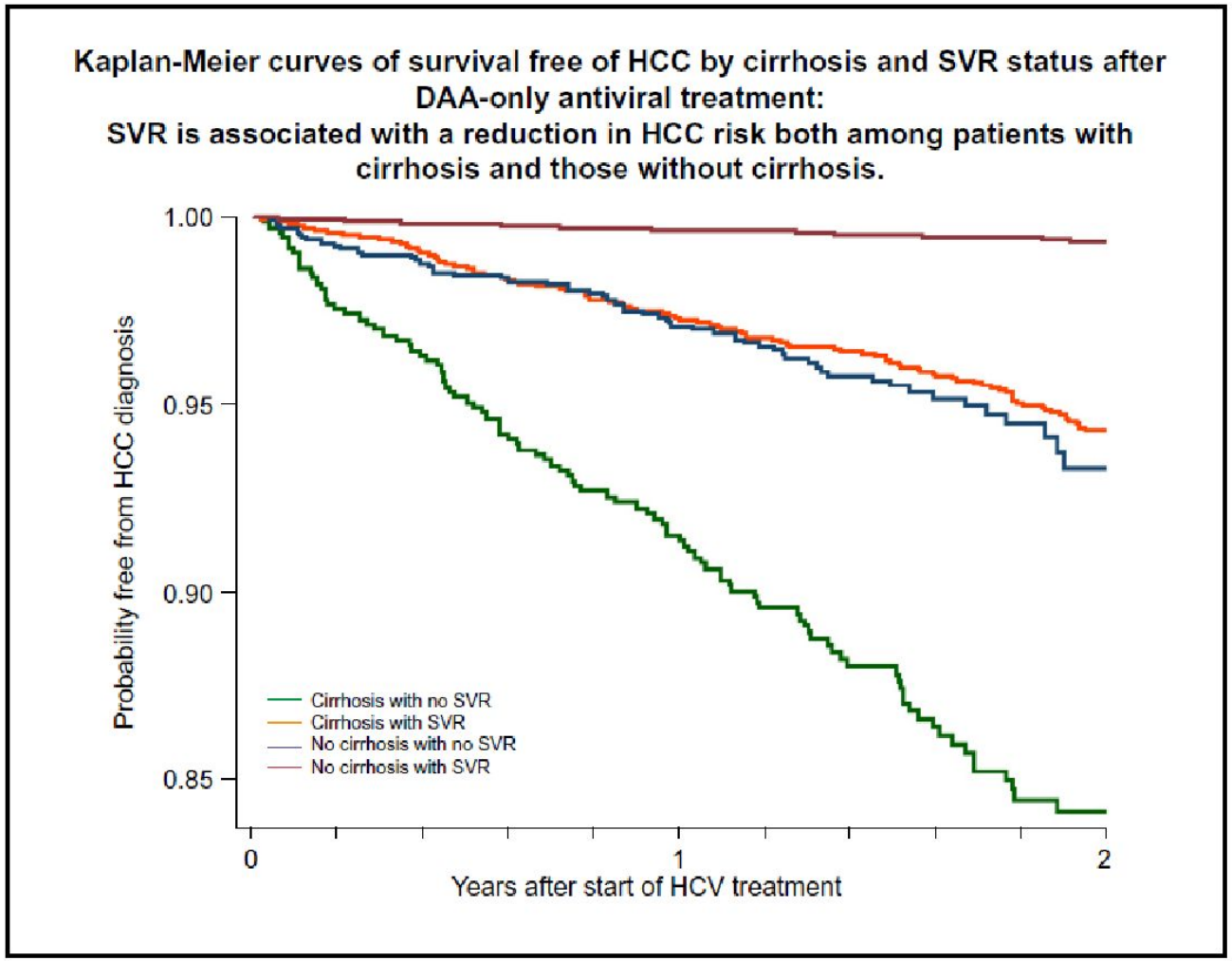
21948 veterans treated with DAAs

90.7% SVR

HCC	SVR	No SVR
Incidence/ 100 person-years	0.92	5.19

Crude HR **0.18**

Adjusted HR **0.29**



Ioannou, J Hep 2018; 68:25-32

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Recommendations for HCC Surveillance after SVR

1. **Ongoing HCC surveillance (with twice-yearly ultrasound +/- AFP) should be done for all patients with F3 or cirrhosis post-SVR**
2. **HCC surveillance is not recommended for F0-F2 post-SVR**
3. **Intensification of HCC screening frequency in immediate post-SVR period is not recommended**

Jacobson, Gastroenterology 2017; 152:1578-87
AASLD/IDSA HCV Guidelines www.hcvguidelines.org

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Other post-SVR follow up

1. **Endoscopic screening for varices for all patients with cirrhosis, independent of SVR**
2. **If negative, repeat EGD at 2-3 years post-SVR; if negative then, may d/c screening on an individual basis**
3. **Patients should be counseled regarding sources of other liver injury (alcohol, fatty liver, hepatotoxins) and should be evaluated for these if liver enzymes remain elevated**

Jacobson, Gastroenterology 2017; 152:1578-87
AASLD/IDSA HCV Guidelines www.hcvguidelines.org

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HEPATITIS B

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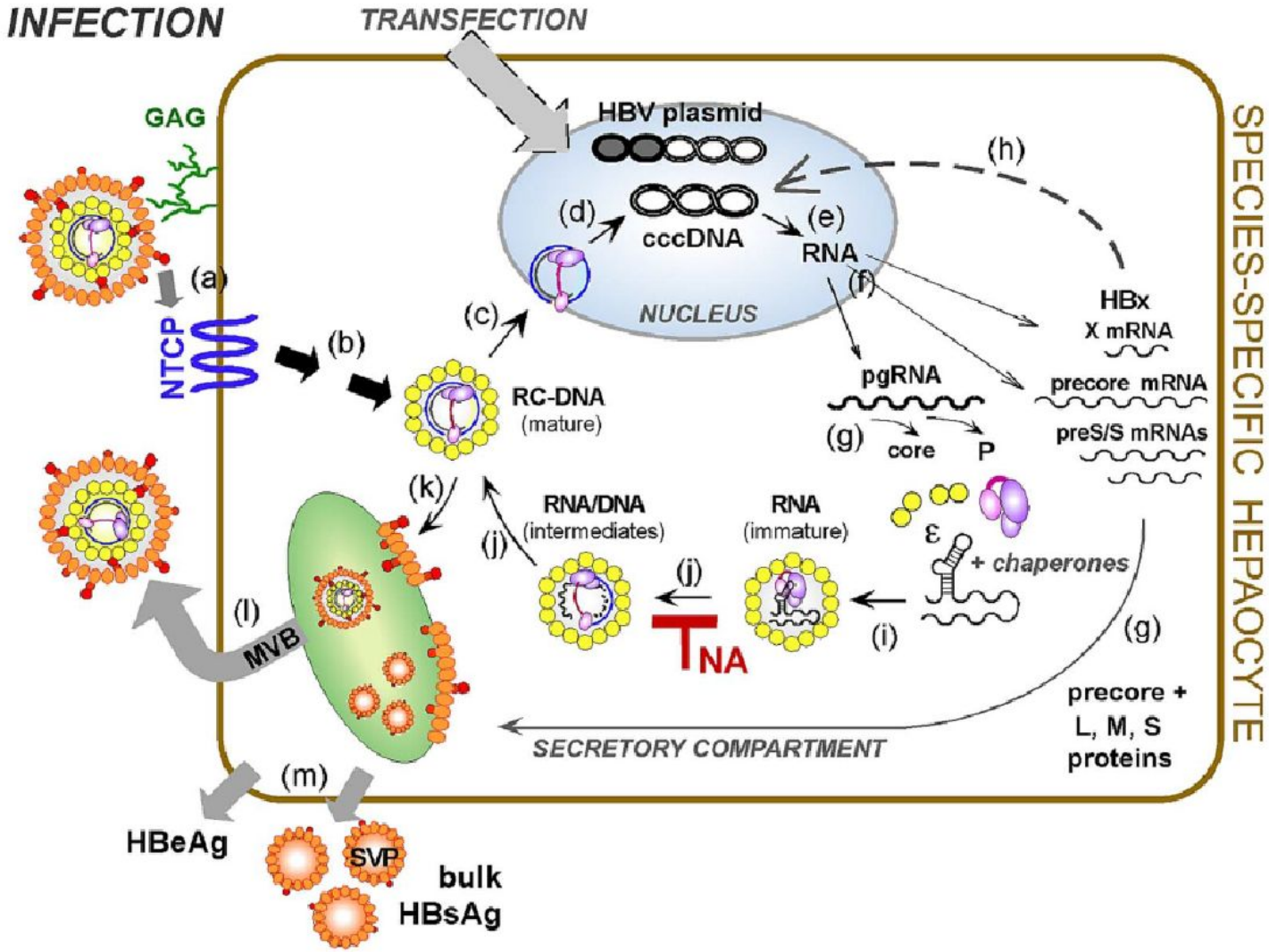
Hepatitis B Cannot be Cured



Nassal, Gut 2015; 64:1972-84

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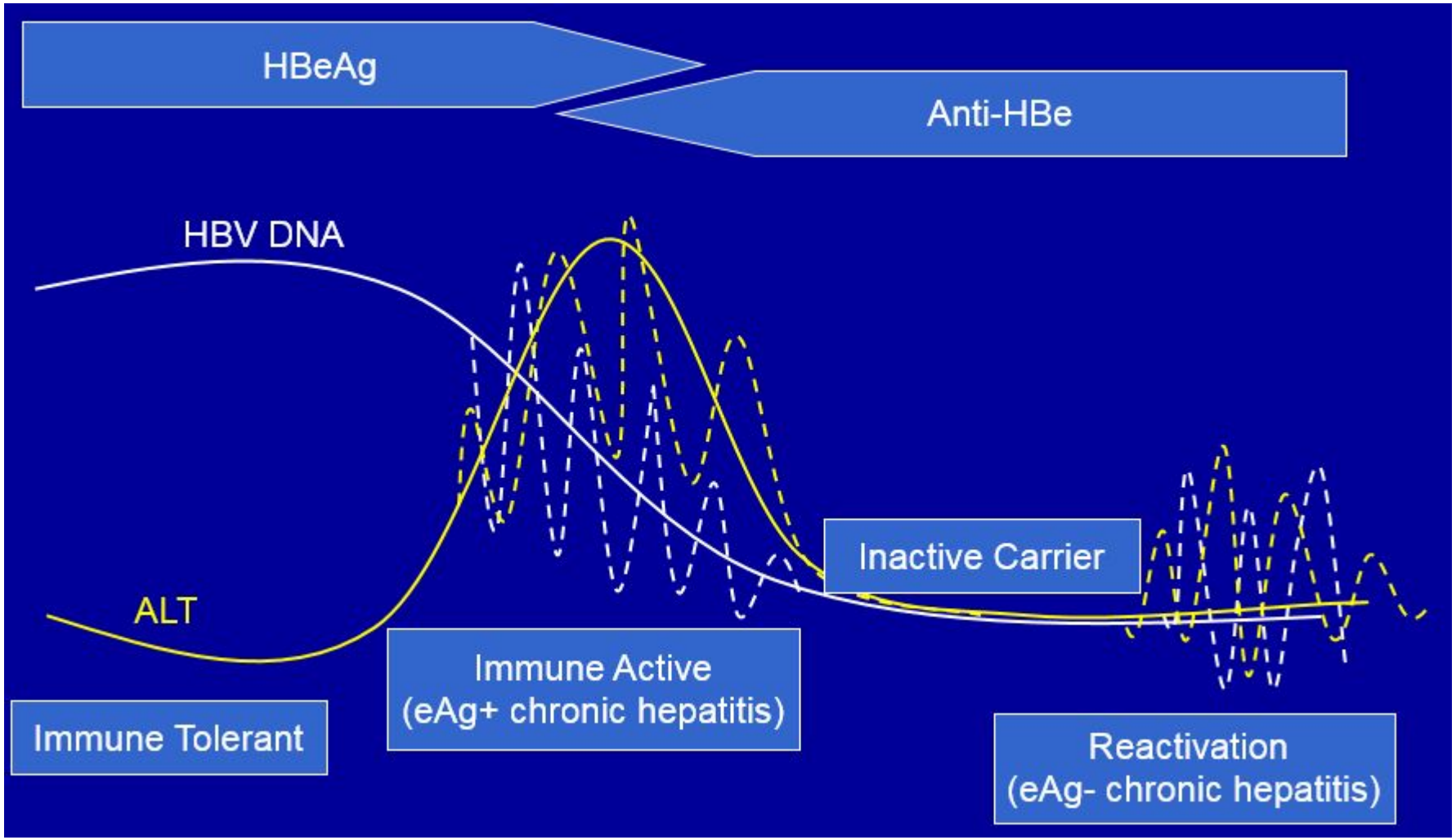
Goals of Antiviral Therapy

- To decrease morbidity and mortality related to CHB
- Sustained suppression of HBV replication associated with ALT normalization, loss of HBeAg and improvement in liver histology
- "immunological cure": HBsAg loss and sustained HBV DNA suppression

Terrault, AASLD HBV Guidelines 2016; Hepatology 63: 261-283

Chronic Hepatitis B (sAg+)



Adapted from Yim, Hepatology 2006; 43:S173-181

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Establishing a Baseline

HBeAg/anti-HBe status

HBV DNA level by PCR

ALT/AST elevation

Presence of Clinical Cirrhosis

- By history/physical and lab work
- Jaundice, ascites, palmar erythema, spider angiomas
- Low platelets, prolonged coagulation parameters, low albumin

Noninvasive assessment of fibrosis

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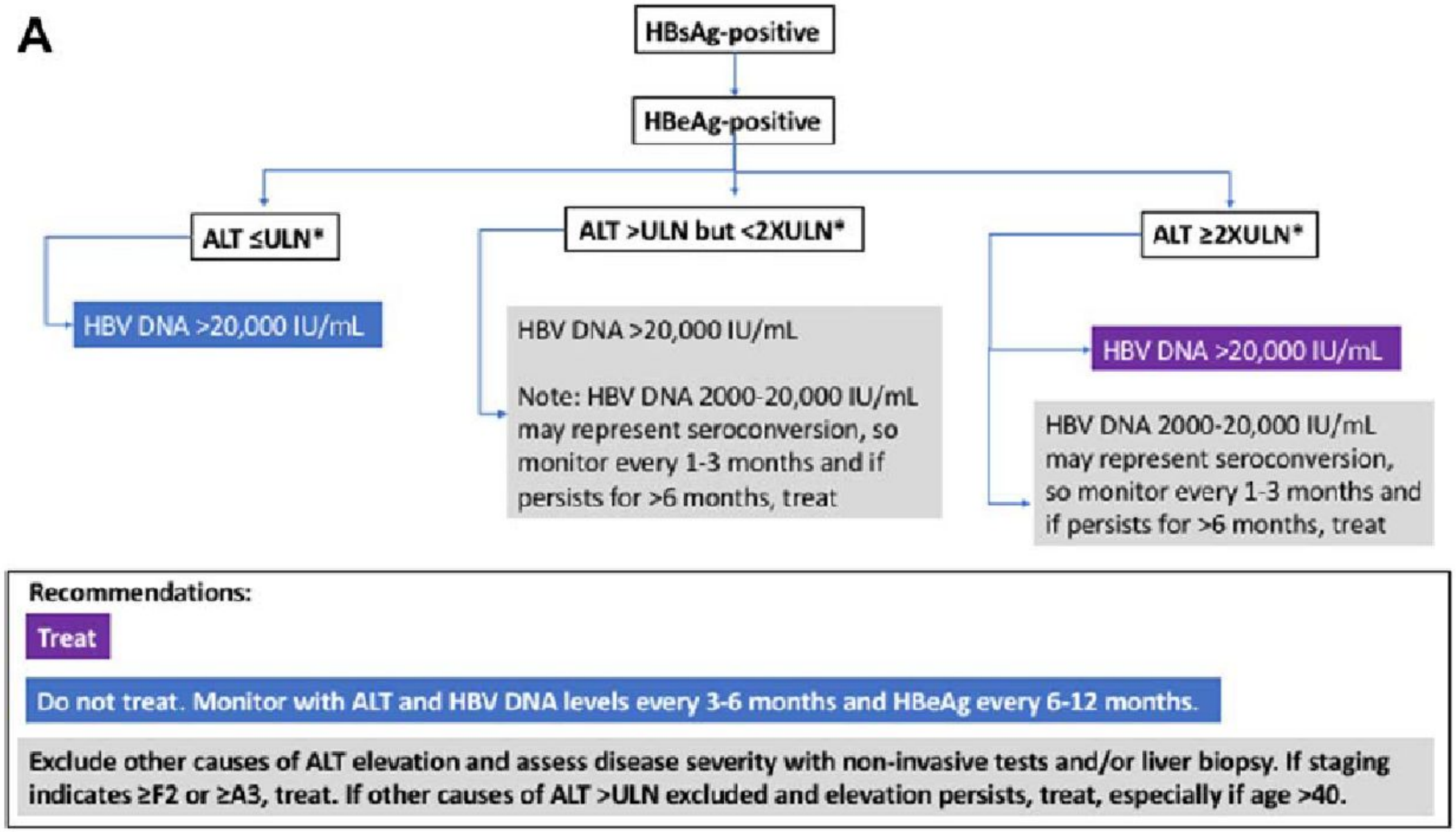
Monitoring of Chronic Hepatitis B: e-antigen positive



Terrault, Hepatology 2018; 67: 1560-98

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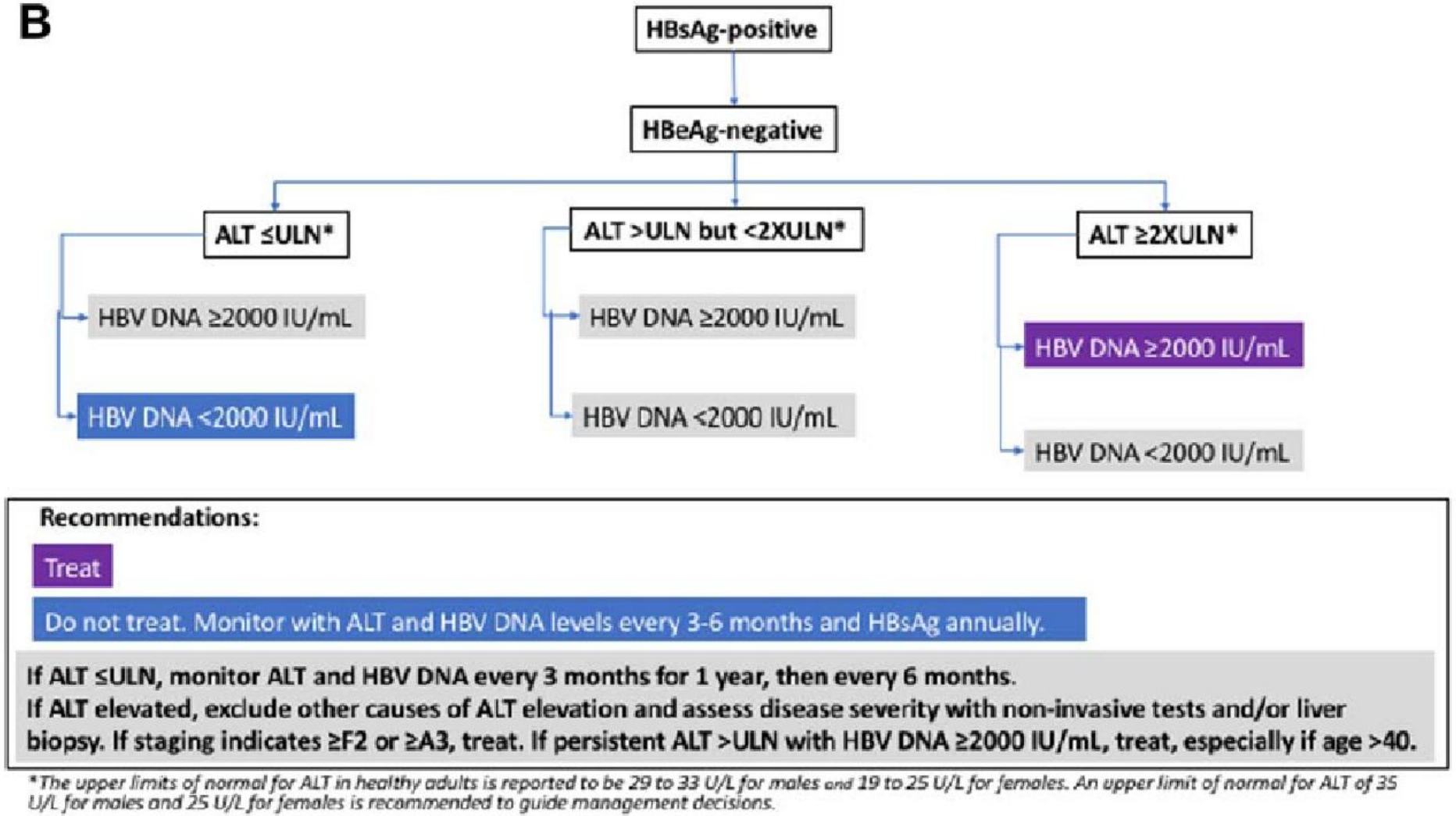
Monitoring of Chronic Hepatitis B: e-antigen Negative



Terrault, Hepatology 2018; 67: 1560-98

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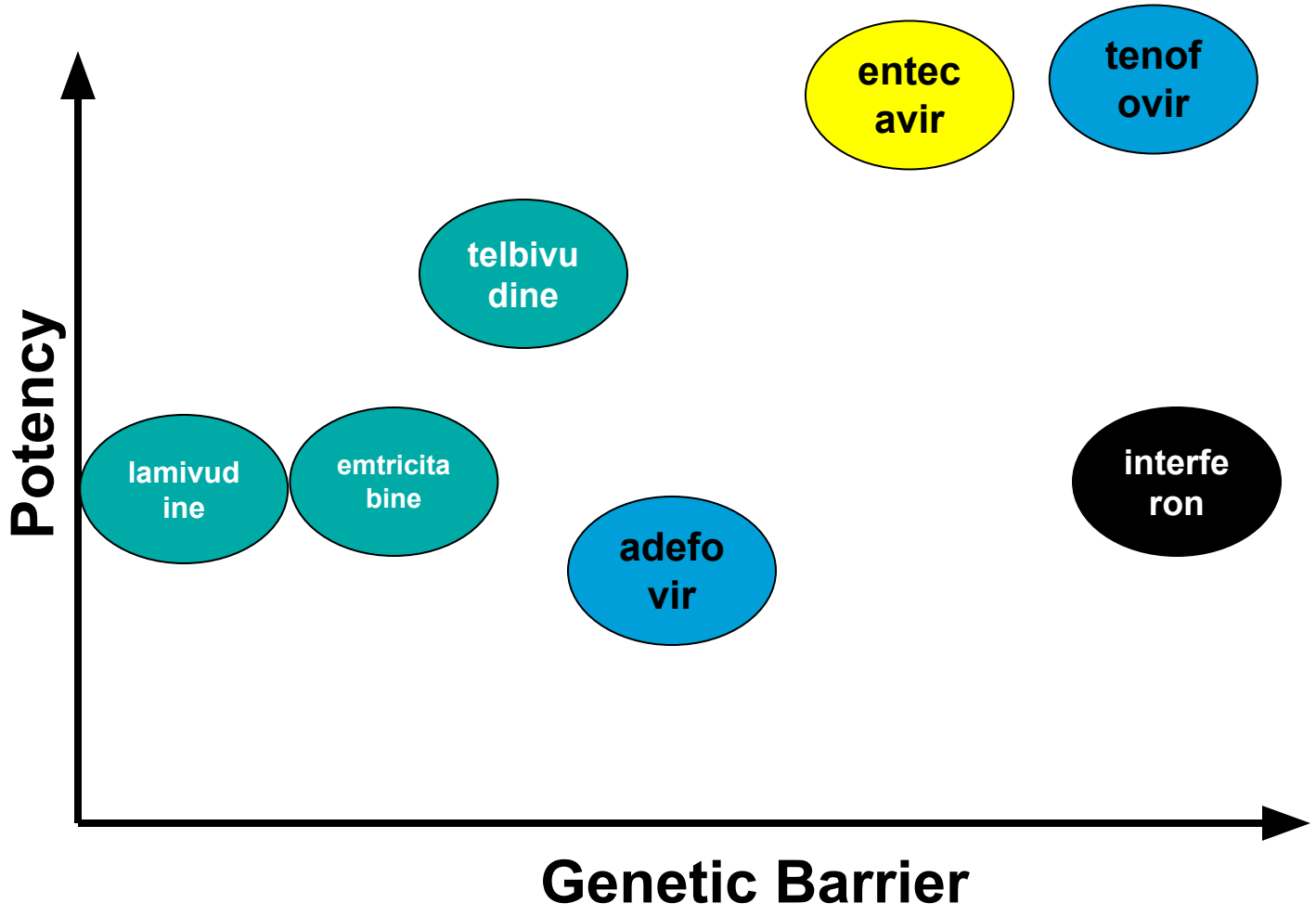
Consider Potency and Potential for Resistance



Adapted from Soriano, AIDS 2008; 22: 1399-1410

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Entecavir (Baraclude)

- Analogue of 2’-deoxyguanosine
- Inhibits HBV replication at 3 different steps
  - Priming of HBV DNA polymerase
  - Reverse transcription of negative strand HBV DNA from pregenomic RNA
  - Synthesis of positive strand HBV DNA

- More potent than lamivudine or adefovir
  - Effective against lamivudine-resistant HBV though activity is lower compared to wild-type HBV

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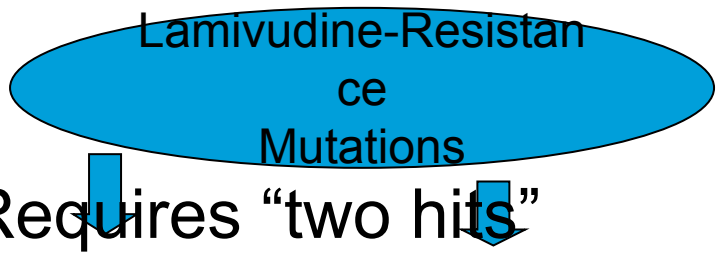
Entecavir Resistance



- Requires “two hits”
- M204V/I +/- L180M as first hit
  - 8 to 10 fold dec in susceptibility to ETV vs wild-type
- Then mutation in I169, T184, S202 or M250
  - These mutations on their own have minimal effect on susceptibility to entecavir
- In presence of M204V/I, one of these leads to 10-250 fold decrease in ETV susc
- M204V/I + 2 mutations 500-1000 fold decrease in ETV susceptibility

Tenney, AAC, 2004; 48:3498-507
Riddick, J Hep 2008; 48:895-902

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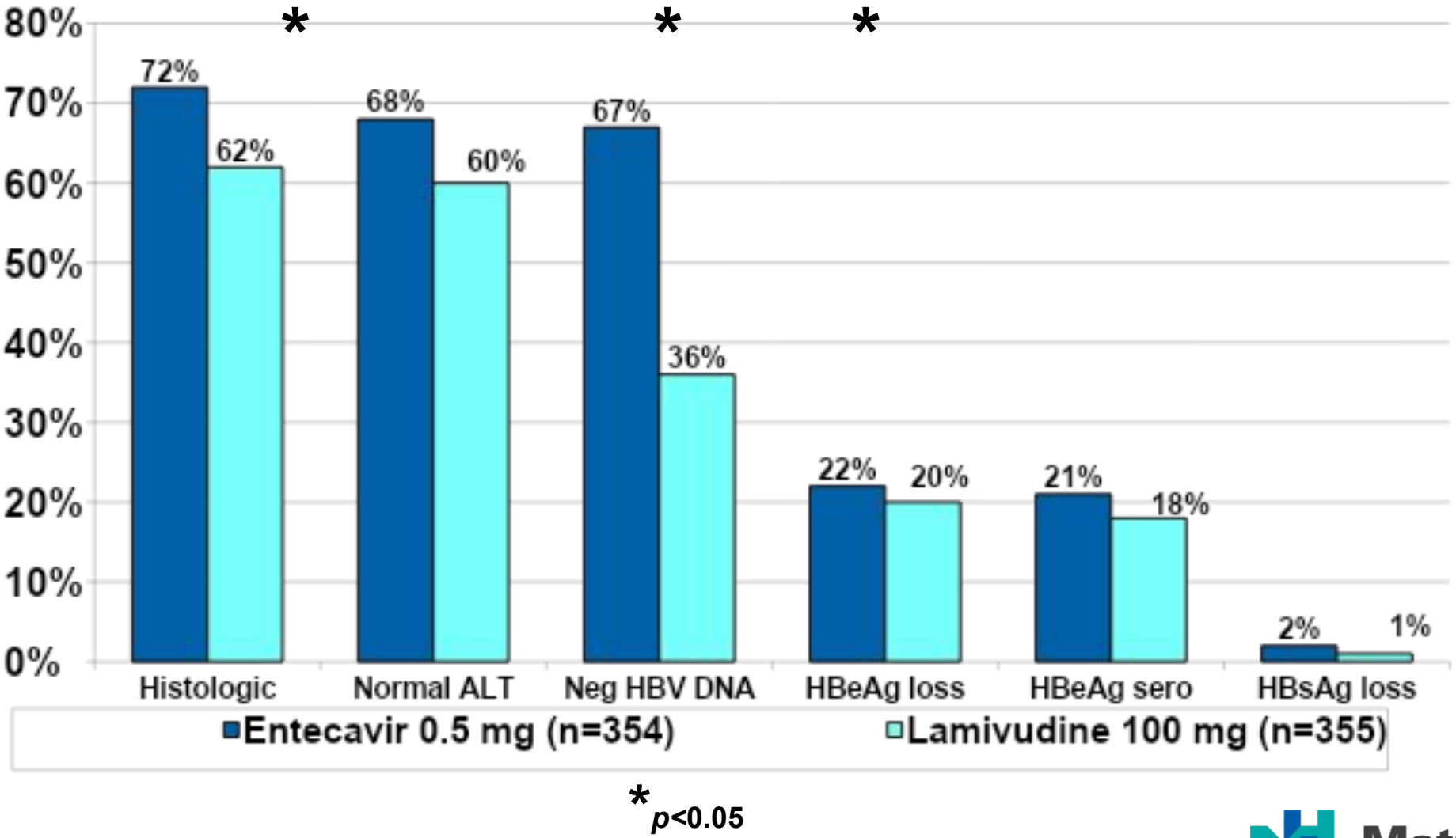
Entecavir in HBeAg+ Chronic Hepatitis B: Week 48



*$p<0.05$

Chang, NEJM 2006; 354:1001-10

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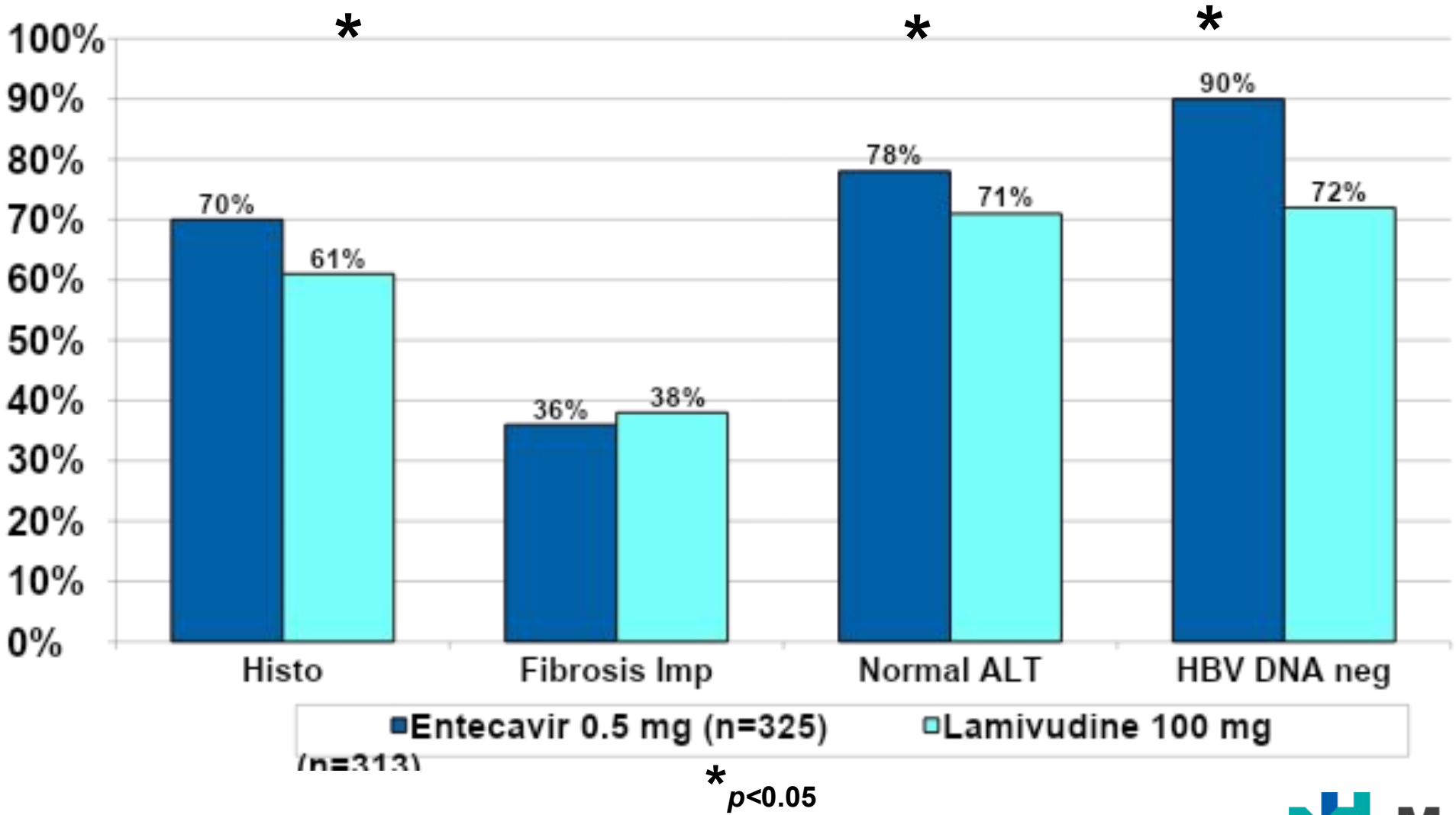
Entecavir in HBeAg- Chronic Hepatitis B: Week 48



Lai, NEJM 2006; 354:1011-20

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Tenofovir DF (Viread) and Tenofovir AF (Vemlidy)

TDF approved for hepatitis B in 2008

TAF approved for hepatitis B in 2016 (25 mg daily)

Effective against multiple HBV genotypes A-H

No confirmed reports of resistance selection during treatment with TDF or TAF for CHB

Inhibits viral polymerase by direct binding, after incorporation into DNA chain

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Phase 3: TAF for HBeAg+ Chronic Hepatitis B

	TAF (N=581)	TDF (N=292)	*P*
HBV DNA<29	371 (64%)	195 (67%)	0.25
HBeAg loss	78/565 (14%)	34/285 (12%)	0.47
HBeAg seroconversion	58/565 (10%)	23.285 (8%)	0.32
HBsAg Loss	4/576 (1%)	1/288 (<1%)	0.52
sAg seroconversion	3/576 (1%)	0	0.22
ALT normalization, AASLD criteria	257/572 (45%)	105/290 (36%)	0.014
Virologic breakthrough	N=14	N=12	

Chan, Lancet Gastro Hep 2016; 1:185-95

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Risk of HCC in Chronic Hepatitis B

Population Group	Incidence of HCC
Hepatitis C: Cirrhotics only	3-5%/year
Hepatitis B	
Asian male carriers over age 40	0.4-0.6%/year
Asian female carriers over age 50	0.3-0.6%year
HBV carrier with FMH of HCC	Higher than without FMH
African/North American Blacks	HCC occurs at a younger age
Cirrhotic hepatitis B carriers	3-8%/year

Marrero, AASLD Guidelines on HCC, 2018
www.aasld.org

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HCC Surveillance in Chronic Hepatitis B

Who to screen

Asian men>40, Asian women>50

Hepatitis B with cirrhosis

Family h/o HCC

Africans >20 yo

North American Blacks with HBV

Any carrier over 40 with persistent or intermittent ALT elevation or high HBV DNA level > 2000 IU/mL

Ultrasound q6 months preferred: best sens, spec, diagnostic accuracy

Consider AFP q6 months if US not available or limited experience at center where US performed

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HEPATITIS A

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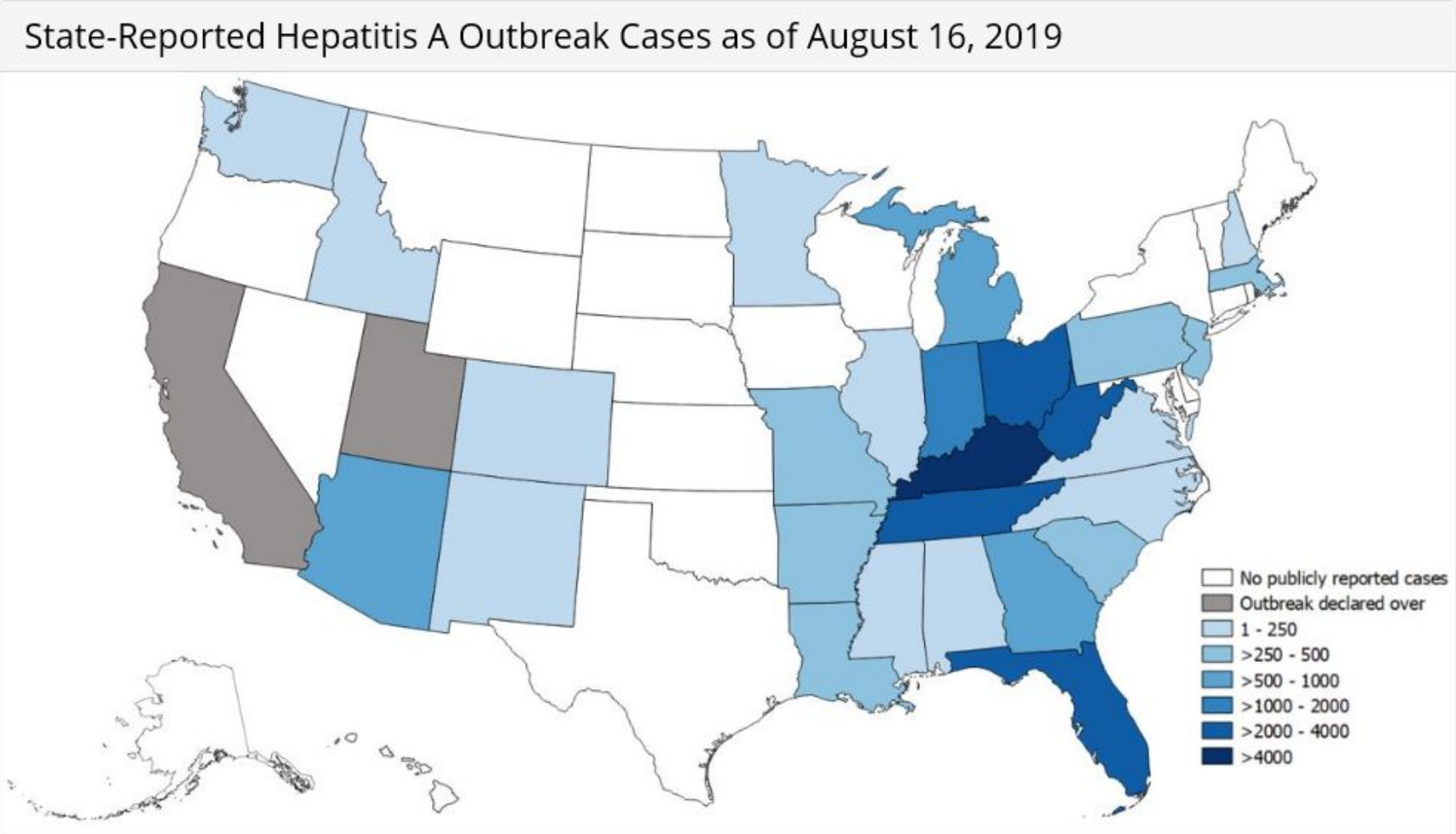
Multistate Outbreak of HAV



29 states

24280 cases

14525 (60%) hospitalizations

236 deaths

www.cdc.gov
accessed 8/23/19

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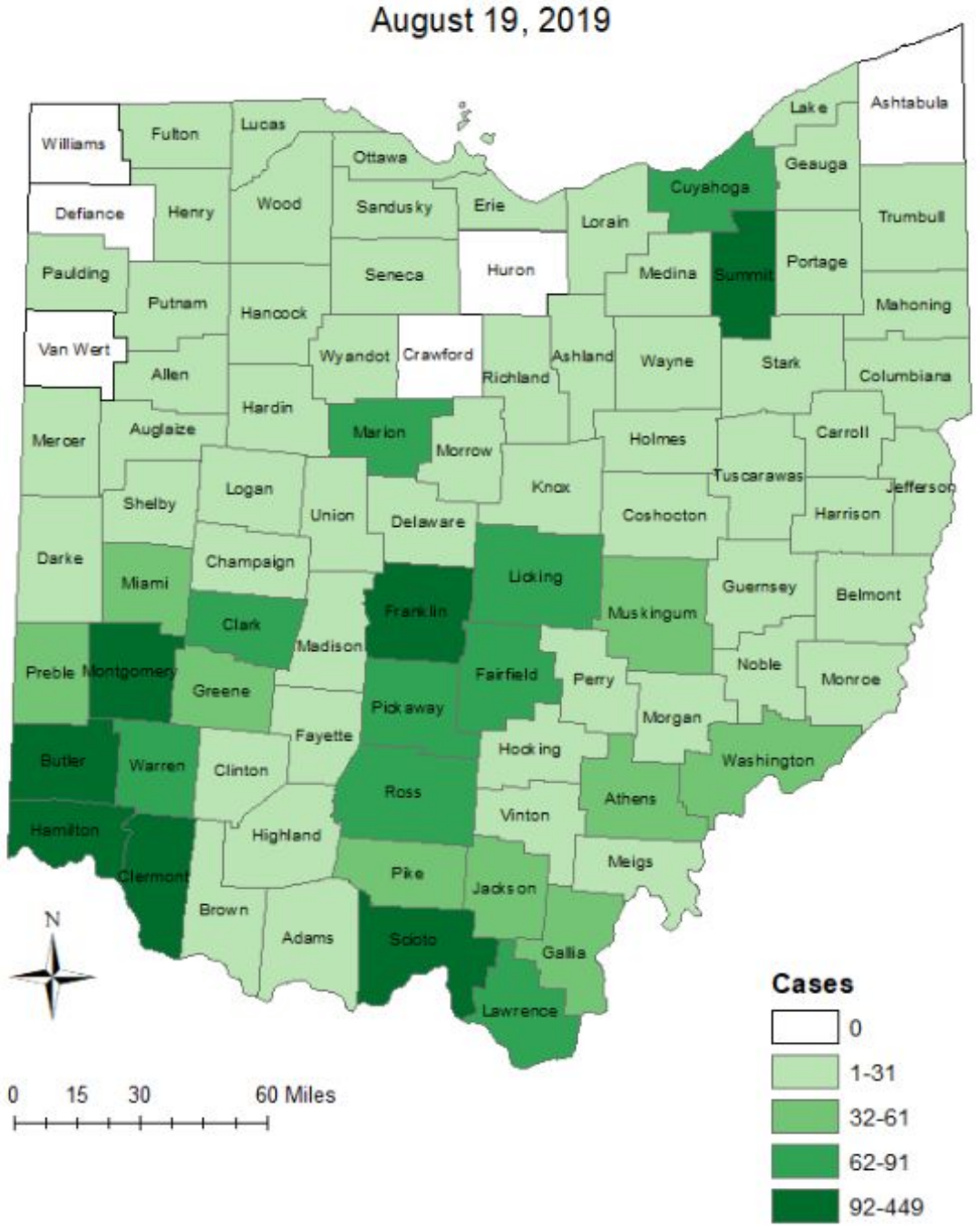
Cases in Ohio

- 3256 total cases
- 1/5/18 to 8/12/19
- 1988 (61%) hospitalizations
- 15 deaths
- 82/88 (93%) of counties with cases



https://odh.ohio.gov accessed 8/23/19

Current Outbreak

- Past outbreaks have been driven by asymptomatic children or were related to contaminated commercial food products
- Current outbreak: most cases have occurred in PWUD and persons experiencing homelessness
  - 57% of cases in CA, KY, MI, UT reported drug use, homelessness or both
  - 54% of cases had an indication for vaccination before becoming infected
- Person-to-person spread has fueled the outbreak
  - Unsafe sanitary conditions, specific sexual contact or practices
  - Parenteral transmission through contaminated needles or paraphernalia
- Public health response has included vaccination campaigns in jails, syringe service programs, drug treatment facilities and homeless shelters, homeless encampments

Foster, MMWR 2018; 67: 1208-10

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Hepatitis A Vaccine Recommendations 2019

- All children age 12-23 months
- Persons traveling to or working in countries with high or intermediate endemicity
- Persons with close contact with international adoptees from countries with high or intermediate endemicity during first 60 days of arrival
- MSM
- Users of injection and non-injection drugs
- Persons with chronic liver disease
- Persons with clotting factor disorders
- Persons who work with HAV-infected primates or with HAV in research lab
- Anyone who wishes to obtain immunity
- **Feb 2019: persons experiencing homelessness**

MMWR 2019: 68: 153-156

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Post-Exposure Prophylaxis

Recent exposure to Hep A who have not received HAV vaccine previously should receive a single dose of single-antigen vaccine or immune globulin as soon as possible

Take into account patient characteristics associated with more severe hepatitis A

For healthy persons aged 1-40, vaccine preferred to immune globulin

Age >40, immune globulin is preferred

IG also preferred for immunocompromised, chronic liver disease and when vaccine contraindicated

Persons receiving IG should also receive vaccine

MMWR, 2007

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Post-Exposure Prophylaxis

Passive immunization through immune globulin, either IVIG or IM (IM preferred for hep A)

Concentrations of HAV IgG are below the level of detection of most diagnostic tests

When administered within 2w after an exposure, 80-90% effective in preventing hepatitis A

TABLE 1. Recommended doses of immune globulin (IG) for hepatitis A preexposure and postexposure prophylaxis

Setting	Duration of coverage	Dose (mL/kg)*
Preexposure	Short-term (1–2 mos)	0.02
	Long-term (3–5 mos)	0.06†
Postexposure		0.02

Contraindicated in IgA deficiency (anaphylaxis); OK in pregnancy and lactation

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Efficacy of HAV Vaccine vs Immune Globulin

Table 3. Outcomes among Recipients of Hepatitis A Vaccine and Recipients of Immune Globulin.*

End Points	Per-Protocol Population		Modified Intention-to-Treat Population†		Relative Risk (95% CI)	
	Vaccine Group (N=568)	Immune Globulin Group (N=522)	Vaccine Group (N=740)	Immune Globulin Group (N=674)	Per-Protocol Population	Modified Intention-to-Treat Population
	number (percent)					
Clinical						
Primary						
Any symptom plus IgM-positive and ALT ≥ twice ULN	25 (4.4)	17 (3.3)	26 (3.5)	18 (2.7)	1.35 (0.70–2.67)	1.32 (0.69–2.55)
Secondary						
Any symptom plus IgM-positive and ALT ≥ twice ULN or HAV RNA–positive on PCR‡	29 (5.1)	19 (3.6)	30 (4.1)	20 (3.0)	1.40 (0.76–2.64)	1.37 (0.75–2.54)
Jaundice plus IgM-positive and ALT ≥ twice ULN or HAV RNA–positive on PCR	18 (3.2)	12 (2.3)	19 (2.6)	12 (1.8)	1.38 (0.63–3.14)	1.44 (0.66–3.25)
Subclinical						
Asymptomatic IgM-positive and ALT ≥ twice ULN or HAV RNA–positive on PCR	20 (3.5)	16 (3.1)	26 (3.5)	18 (2.7)	1.15 (0.57–2.37)	1.32 (0.69–2.55)
Clinical plus subclinical	49 (8.6)	35 (6.7)	56 (7.6)	38 (5.6)	1.29 (0.82–2.05)	1.34 (0.87–2.08)

Victor, NEJM, 2007; 357:1685-94

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Recap/Take Home Points: Hepatitis C

Patients who achieve SVR and have a negative viral load 48 weeks after completion of therapy do not need any further viral load testing

Patients with F0-F2 who achieve SVR do not require any further follow up

For those with F3-F4 before treatment, HCC surveillance should be continued lifelong, even if post-treatment liver stiffness measurement shows improvement

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Recap: Hepatitis A

Ongoing outbreak of HAV nation-wide, with a hotspot in Ohio

Vaccination of at-risk individuals, including those unstably housed, is recommended

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QUESTIONS?

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