

**Rush University Medical Center** 

# Hepatitis Delta: An Update in Epidemiology, Screening and Therapy

10<sup>th</sup> Annual Update on Liver Disease: An Multidisciplinary Approach March 2023

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## Agenda:

- 1 Outline the natural history and epidemiology of HDV
- 2 Discuss current screening guidelines for HDV
- 3 Describe current standard of care therapy for HDV and future treatment options



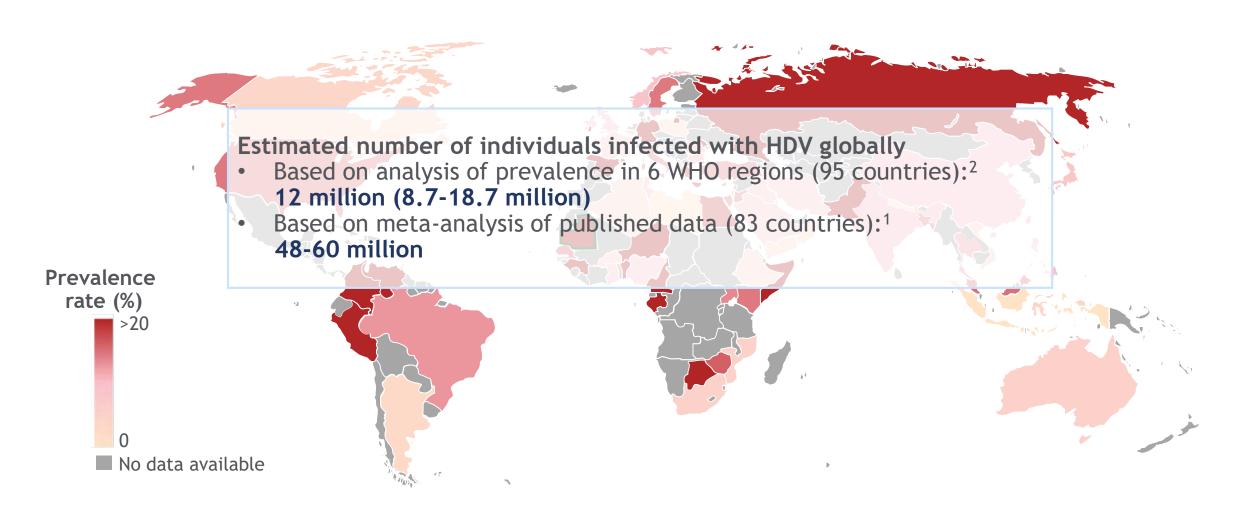
## **Disclosures**

- Consultation: AbbVie, Gilead, Arbutus, Intercept, Salix
- Research Support: AbbVie, Gilead



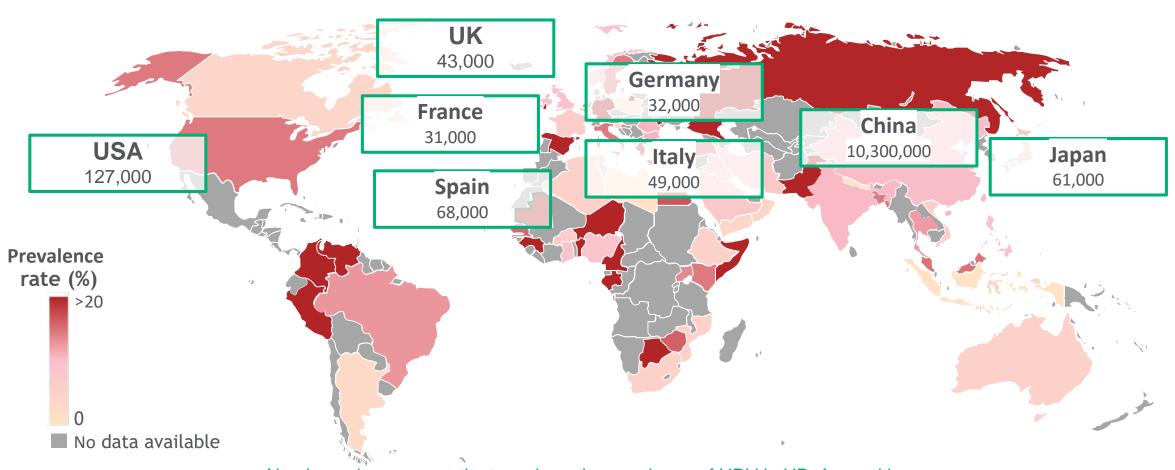
## **Epidemiology and Natural History**

## Approximately 4.5%-13% of HBsAg-positive Carriers Coinfected With HDV<sup>1</sup>



## Estimated number of individuals with HDV in selected countries

An estimated 48-60 million people are infected with HDV worldwide



Numbers shown are patient numbers, ie prevalence of HDV in HBsAg-positive patients.

Miao. J Infect Dis. 2020;221:1677.

# Antibodies to delta antigen in asymptomatic HBsAg positive blood donors in the United States in 1979

- 1,915 asymptomatic blood donors with HBsAg from 49 of 57 regions of the American Red Cross (nine geographic regions of the US and Puerto Rico)
  - Tested for delta antigen, anti-delta, HBeAg and anti-HBe
  - 72 (3.8%) sera had anti-delta activity while none had a detectable level of delta antigen.

## Geographic variation:

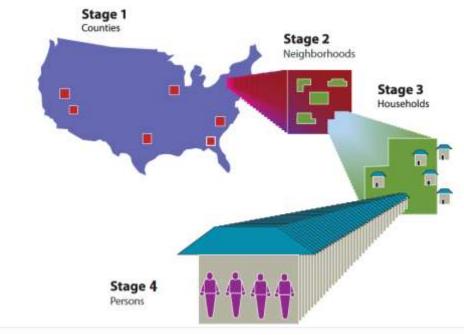
- Higher prevalence of anti-delta (12.1%) was found in San Jose, California (Pacific Region)
- Low prevalence (1.4%) East South Central region covering Alabama, Kentucky, Mississippi and Tennessee
- Not associated with age, sex or blood type of the donor





## National Health and Nutrition Examination Survey

- NHANES designed to assess the health and nutritional status of adults and children in the United States.
- Major program of the National Center for Health Statistics (NCHS) - part of the Centers for Disease Control and Prevention (CDC) - and has the responsibility for producing vital and health statistics
- Began in 1960s and has been conducted as a series of surveys focusing on different population groups or health topics.
- The survey examines a nationally representative sample of about 5,000 persons each year. These persons are located in counties across the country, 15 of which are visited each year.



- All the counties in the United States are divided into 15 groups based on their characteristics. One is selected from each group and together they form the 15 counties in the NHANES survey for the year.
- Within each of the 15 NHANES counties, smaller groups (such as neighborhoods) are formed, and between 20 and 24 of these small groups are selected.
- All the houses or apartments within those selected small groups are identified, and a sample of about 30 households are chosen within each group.
- NHANES will contact the selected household and ask a short set of questions (age, race, and gender) about everyone in the household.



## **NHANES** evaluate US Prevalence of HDV

# Prevalence of hepatitis delta infection in the United States: National Health and Nutrition Examination Survey, 1999-2012

- Participants with a positive test for hepatitis B core antibody + hepatitis B surface antigen → antibody to HDV.
- Data on 71,916 individuals were obtained, with 52,209 (72.6%) receiving HDV testing.
- The overall prevalence of HDV in the United States was 0.02% (10/52209), with a mean age of 52.1 ± 14.0 years and 60% males

0.02% of 52,209 HBsAg+

## Estimate made using 113 HBsAg +

## Prevalence of Hepatitis B and Hepatitis D Virus Infections in the United States, 2011–2016

- Among 21, 832 adults in the 2011-2016 NHANES the estimated prevalence of HBsAg was 0.36% overall and 3.4% in non-Hispanic Asians.
- Prevalence of anti-HDV among persons aged ≥6 years was 0.11% **79% were foreign born**)
- Among adult HBsAg carriers, 42% had antibodies to hepatitis delta virus (anti-HDV).

Prevalence of Ongoing Hepatitis B Virus Infection and Seroprevalence of Hepatitis D Virus Infection in the Noninstitutionalized US Civilian Population Aged ≥18 Years—National Health and Nutrition Examination Survey, 2011–2016

		Overall A	Adult Population				Anti-HDV Among Adult	
		HBsAg			Anti-HD	v		HBsAg Carriers
Characteristic	No. Tested	No. Positive	% (95% CI)	P Value	No. Positive	% (95% CI)	P Value	% (95% CI)
Total	16 143	113	0.36 (0.29- 0.46)		43	0.15 (0.10- 0.23)		42 (29–56)

## Given geographic variation- this may not be representative

-					E	<u>Stimate made</u>	using 113 H	lBsAg +
Prevalence of hep	Race/ethnicity <sup>b</sup>			<.0	<.001		01	D Virus
States: National H Survey, 1999-2012  O Participants with	Asian, non- Hispanic	1964	70	3.37 (2.62– 4.32)	29	1.51 (1.03– 2.20)	45 (30– 60)	16 NHANES the ).36% overall
antibody + hep HDV .	Other races/ethnicities	14 179	43	0.19 (0.14– 0.25)	14	0.07 (0.03– 0.16) <sup>a</sup>	39 (19– 63)	ns aged ≥6 years
o Data on 71,916-52,209 (72.6%)	Birthplace			<.0	01	<.0	01	d antibodies to
<ul> <li>The overall pre was 0.02% (10, 14.0 years and</li> </ul>	US born	11 227	33	0.16 (0.10- 0.24)	9	0.05 (0.02– 0.15) <sup>c</sup>	33 (13– 63) <sup>a</sup>	rus Infection in the ition Examination Survey, 2011–
0.02%	Foreign born	4916	80	1.30 (0.96– 1.76)	34	0.60 (0.40– 0.90)	46 (33– 60)	Anti-HDV Among Adult HBsAg Carriers P Value % (95% CI) 42 (29–56)

# Delta hepatitis within the Veterans Affairs medical system in the United States: Prevalence, risk factors, and outcomes

- Nationwide retrospective study of all veterans who tested positive for HBsAg from October 1999 to December 2013.
- Only 8.5% of 25,603 with positive HBsAg were tested for anti-HDV of which 3.4% (73/2175) were positive
- 8.2% (6/73) of underwent confirmatory PCR testing.
  - Fitting a predefined high-risk profile (abnormal ALT with suppressed HBV DNA titers) was strongly associated with testing positive for HDV (OR 3.2, 95%CI 1.4–7.5).
  - Most (59%) of HDV-positive patients were HCV coinfected.

Variable	Unadjusted OR (95% CI)	p value 0.49	
Age (per 1 year increase)	0.99 (0.99-1.00)		
White	1.2 (1.1-1.3)	< 0.001	
Male	1.8 (1.4-2.3)	< 0.001	
HBeAg tested	12.3 (9.1-12.2)	< 0.001	
Anti-HBe tested	8.9 (7.8-10.0)	< 0.001	
HBV DNA tested	3.8 (3.5-4.2)	< 0.001	
HCV Ab tested	2.2 (1.9-2.5)	< 0.001	
HIV tested	2.6 (2.3-2.8)	< 0.001	
HBclgM tested	2.1 (1.9-2.3)	<0.001	
HBclgM*	3.0 (2.6-3.5)	< 0.001	
HBeAg*	1.7 (1.6-1.9)	< 0.001	
HCV Ab⁺	0.86 (0.76-0.97)	0.014	
Alcohol abuse	0.50 (0.45-0.55)	< 0.001	
Substance abuse	1.2 (1.0-1.3)	0.007	
Cirrhosis	2.5 (2.2-2.8)	< 0.001	
High risk profile	1.3 (1.1-1.5)	0.002	
Oral nucleoside therapy	3.1 (2.9-3.4)	< 0.001	
Interferon therapy	2.4 (1.9-3.1)	< 0.001	
Specialty care (GI/ID)	3.3 (3.0-3.6)	< 0.001	
Gastroenterology/hepatology	4.0 (3.7-4.5)	< 0.001	
Infectious disease	2.4 (2.1-2.7)	< 0.001	

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# Populations at High Risk of HDV Infection

## Groups at high risk of HDV infection (in order of greatest risk)<sup>1</sup>

People who inject drugs

Commercial sex workers

Men who have sex with men

**HCV-infected individuals** 

Cirrhosis patients

HIV-infected individuals

**HCC** patients

Hemodialysis recipients

Additional factors contributing to increased HDV prevalence<sup>2,3</sup>

Migrants from endemic countries

No HBV vaccination - If patient receives and responds to HBV vaccination it will prevent HDV

Mother to baby - HDV transmission via this route is rare, but increases risk of HBV

1. Stockdale. J Hepatol. 2020;73:523. 2. https://www.who.int/news-room/fact-sheets/detail/hepatitis-d.
 3.https://www.cdc.gov/hepatitis/hdv/hdvfag.htm#section1

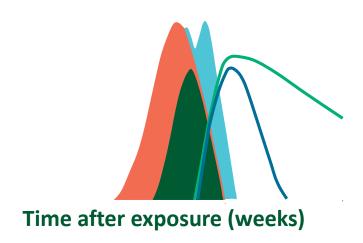
## **HBV** and **HDV** Serology Varies Depending on Timing of **HDV** Infection

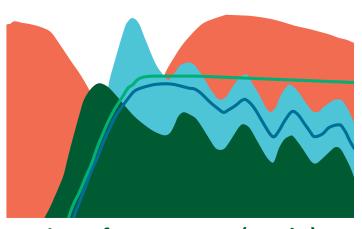
**Simultaneous Coinfection** With HBV and HDV Usually results in spontaneous clearance of both viruses

**HDV Superinfection** in HBV Carrier

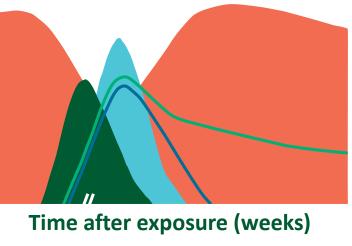
Usually results in persistent viral replication

May occasionally result in **HDV RNA clearance after many yrs** 



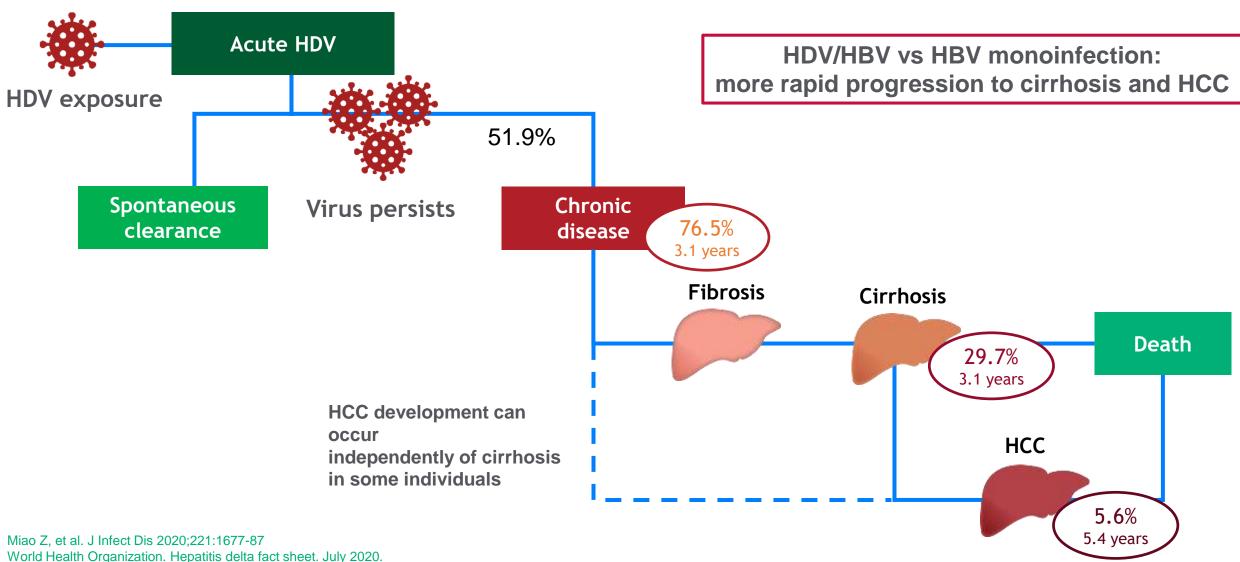






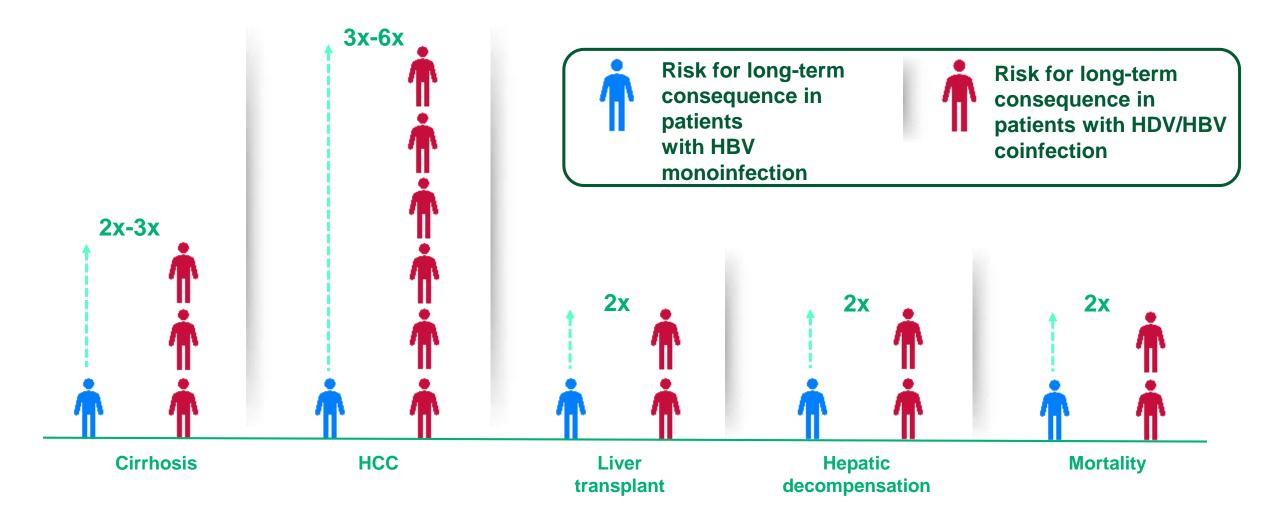


## Clinical Course of Hepatitis Delta



https://www.who.int/news-room/fact-sheets/detail/hepatitis-d. Accessed March 2021.

# Increased Risk for Long-term Consequences of Viral Hepatitis in Patients With HDV/HBV Coinfection vs HBV Monoinfection



# 2 Screening and Diagnosis

## **Testing Recommendations for HDV**

#### **WHOM TO TEST?**

#### **HOW TO TEST?**



- HBsAg+ patients with HDV risk factors
- Low/undetectable HBV DNA and high ALT

- Anti-HDV
- HDV RNA



All patients infected with HBV

NO RECOMMENDATION



Patients with chronic HBV and chronic liver disease

- HDAg or Anti-HDV
- HDV RNA



**NO RECOMMENDATION** 

- Anti-HDV
- HDV RNA

## AASLD Recommendations for HDV Testing in Clinical Practice<sup>1</sup>

HBsAg-positive persons at high risk for HDV infection who should be screened





- Persons born in regions with reported high HDV endemically<sup>a</sup>
  - Africa (West Africa, horn of Africa)
  - Asia (Central and Northern Asia, Vietnam, Mongolia, Pakistan, Japan, Taiwan)
  - Middle East (all countries)
  - Eastern Europe (Eastern Mediterranean regions, Turkey)
  - South America (Amazonian basin)
  - Other (Greenland)

- Persons who have ever injected drugs
- MSM
- Individuals infected with HCV or HIV
- Persons with multiple sexual partners or any history of sexually transmitted disease
- Individuals with elevated ALT or AST with low or undetectable HBV DNA



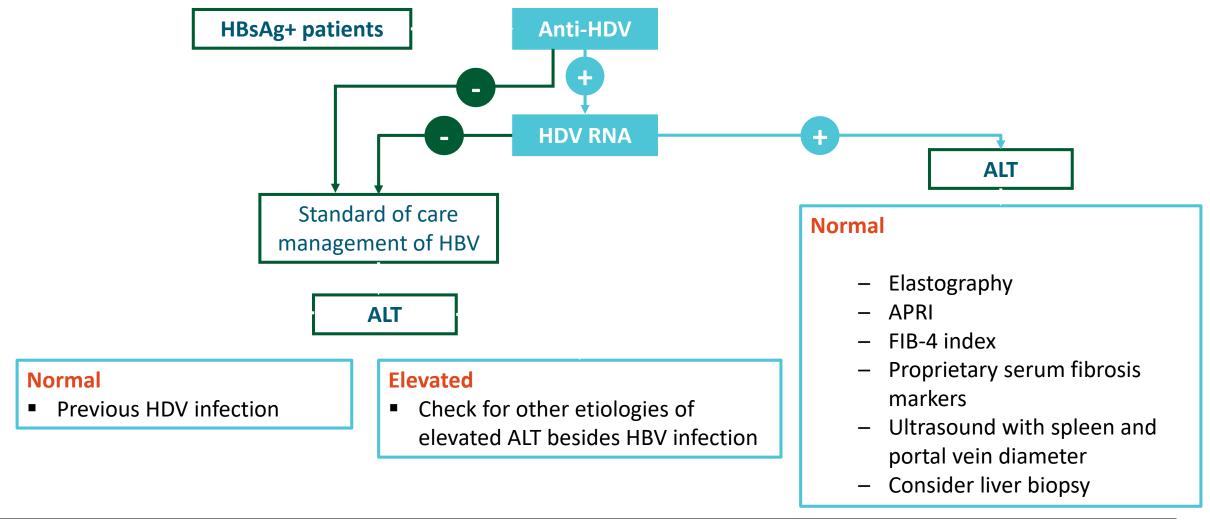
Given the challenges of using risk-based screening, universal screening of all HBsAg-positive persons may be a reasonable alternative.



NORAH TERRAULT AND MARC GHANY<sup>2</sup>



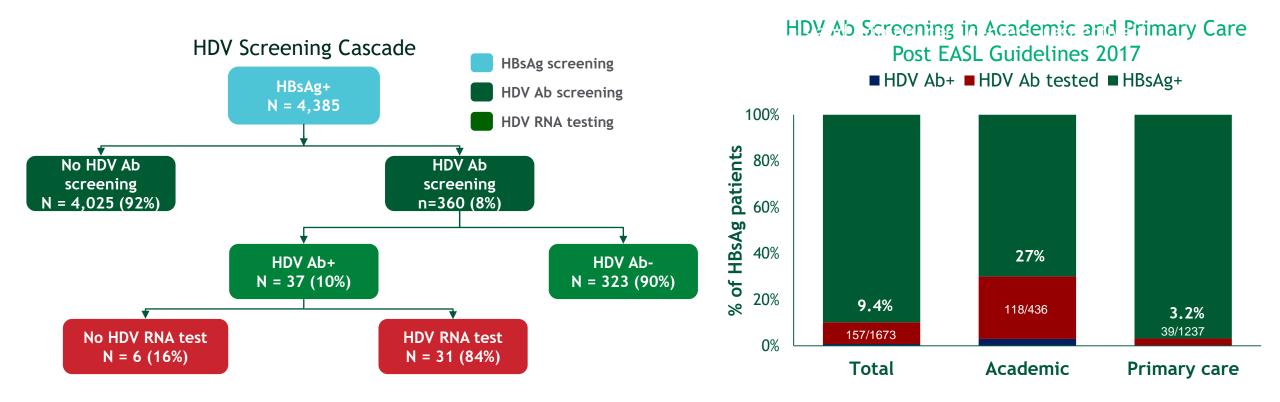
## Algorithm for the Evaluation of HDV





# Screening of HDV in HBsAg+ Patients in Barcelona – Are EASL Guidelines Implemented?

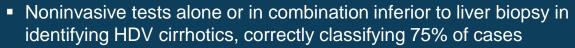
Retrospective analysis of HBsAg+ serum samples from a central laboratory in Barcelona from January 2015 to May 2021



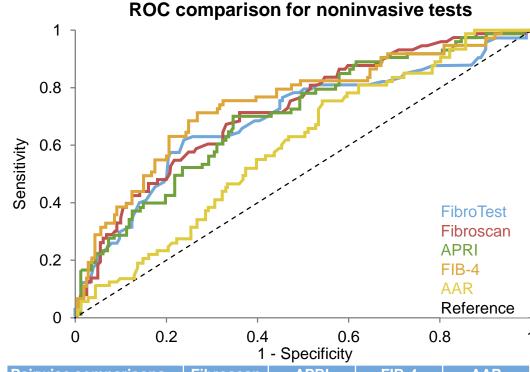
# Limited utility of noninvasive tests for prediction of biopsy-proven cirrhosis in chronic hepatitis D infected patients: Insights from the D-LIVR trial

#### Diagnostic accuracy of noninvasive tests for prediction of cirrhosis

	Cut-off	Cirrhosis n (%)	No cirrhosis n (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Correctly classified n (%)
FibroTest	>0.74	27 (30.7)	19 (8.6)	30.7	91.4	58.70	76.72	228 (74.0)
FIDIOTEST	≤0.74	61 (69.3)	201 (91.4)					
Eibrassan	>13 kPa	36 (46.8)	34 (19.9)	46.8	80.1	51.43	76.97	173 (69.8)
Fibroscan	≤13 kPa	41 (53.2)	137 (80.1)					
APRI	>2	25 (27.2)	22 (9.3)	27.2	90.7	53.19	76.24	240 (72.9)
AFKI	≤2	67 (72.8)	215 (90.7)					
FIB-4	>3.25	27 (29.3)	18 (7.6)	29.3	92.4	60.00	77.11	246 (74.8)
ГІБ-4	≤3.25	65 (70.7)	219 (92.4)					
AAR	>1	12 (12.9)	22 (9.3)	12.9	90.7	35.29	72.64	227 (68.8)
AAK	≤1	81 (87.1)	215 (90.7)					

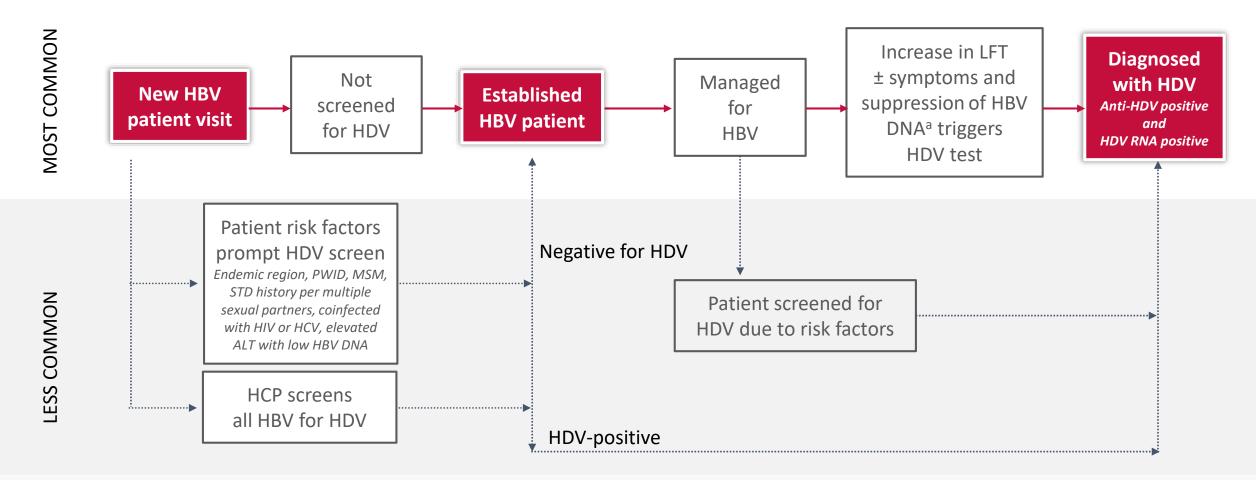


- Cut-off adjustment of individual noninvasive tests does not improve accuracy
- Correct classification of cirrhotic vs non-cirrhotic patients using optimized cutoffs (YI) was best achieved by FIB-4 (73%), followed by FibroTest (71%), LSM and APRI (65%) and AAR (53%)



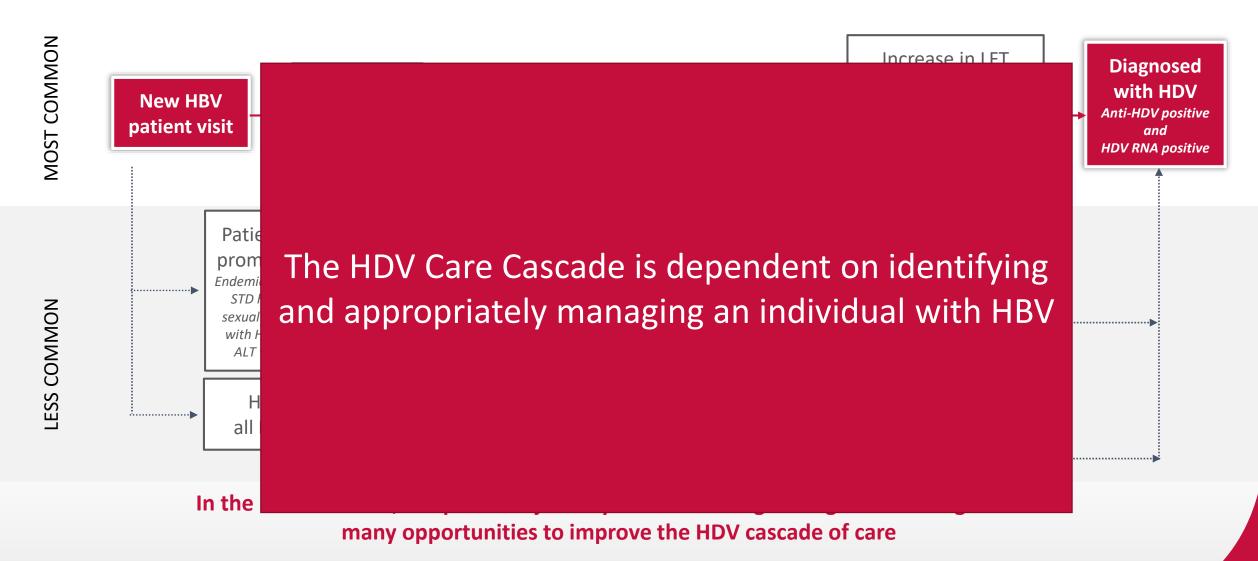
Pairwise co	mparisons	Fibroscan	APRI	FIB-4	AAR
FibroTest	Diff in area	0.03	0.01	0.05	0.09
	Р	0.45	0.81	0.13	0.08
Eibrosoon	Diff in area		0.02	0.02	0.12
Fibroscan	Р		0.63	0.56	0.008
APRI	Diff in area			0.04	0.10
AFKI	Р			0.048	0.04
FIB-4	Diff in area				0.14
Г1D <del>-4</del>	Р				< 0.001

## The HDV Patient Journey in the United States



In the United States, the patient's journey from screening through monitoring reveals many opportunities to improve the HDV cascade of care

## The HDV Patient Journey in the United States



# 3 Therapy

## Back to BC

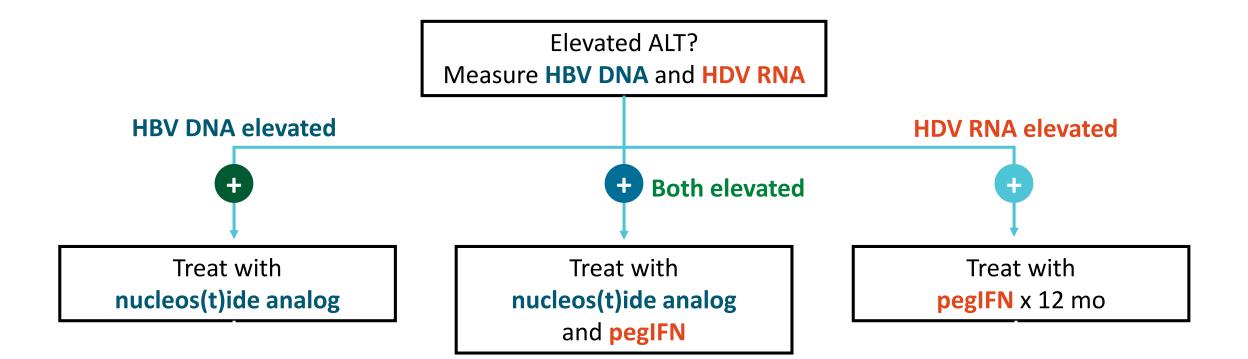
- BC continues to feel well
  - HBsAg positive, HBV DNA negative
  - HDV-Ab positive -→ HDV PCR positive
  - RUQ US without mass
  - Fibroscan with stage 4 fibrosis

- What can we do now?
  - Screen for HCC at 6 month intervals!
  - Consider therapy for HDV +/- HBV

# Guidelines... they're coming

Prior standard of care was PEG

# AASLD Guidance: HDV Treatment Options



 Nucleos(t)ide analogs have no efficacy against HDV infection

- Treatment success with pegIFN at Wk 24 ranges from 23% to 57%
- PegIFN contraindicated in decompensated cirrhosis

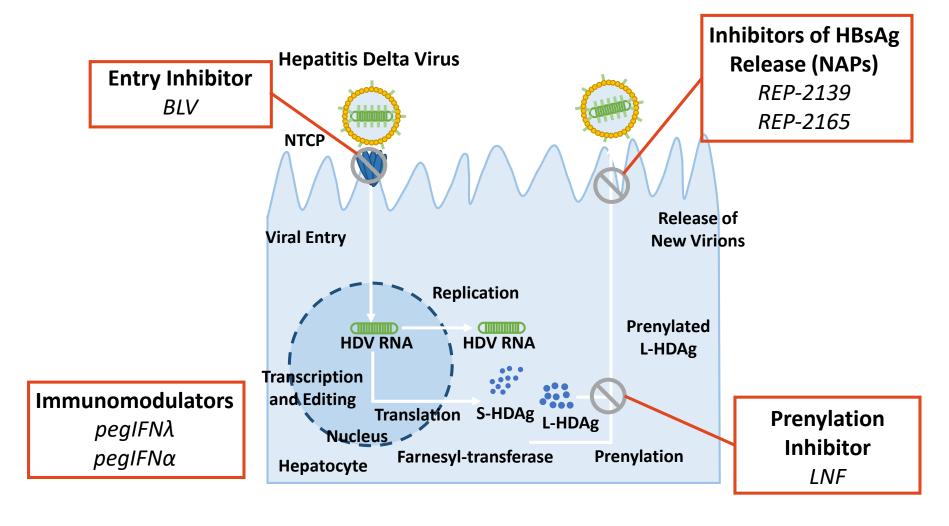
PegIFN contraindicated in decompensated cirrhosis

## PEG-INFa and HDV

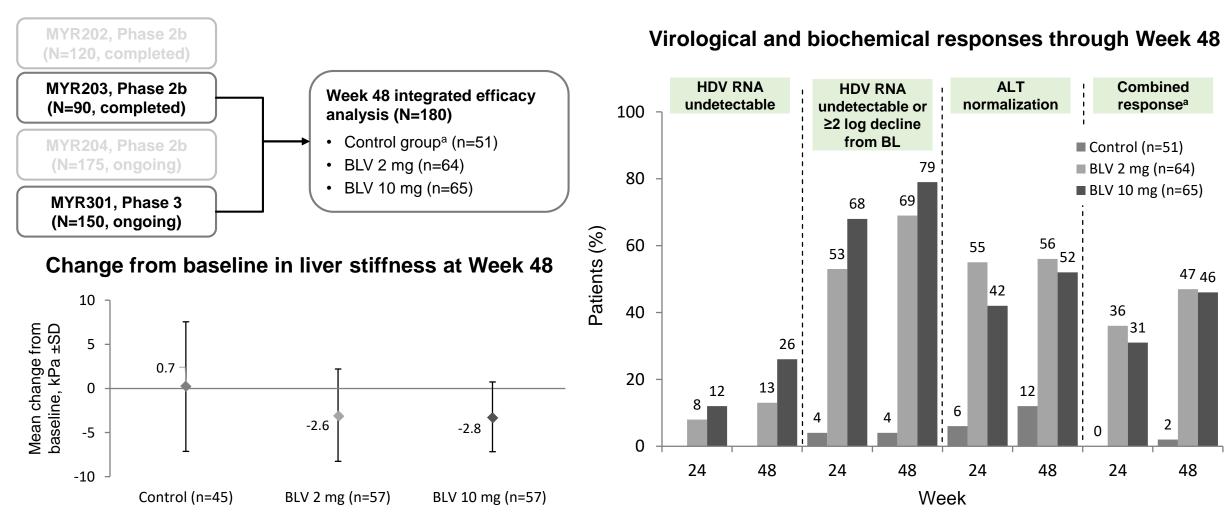
- On-treatment virologic response rates 17–47%.
- 25% HDV RNA negative 24weeks after treatment cessation
- Late relapses beyond week 24 > 50% of responders
  - Monitor all HDV patients as long as HBsAg detectable
  - HBsAg loss in approximately 10% of PegIFNa patients
- Neither NAs nor ribavirin showed significant effects on HDV RNA levels in patients with HDV infection.

# 4 The Future

## Therapeutic Targets for HDV Infection



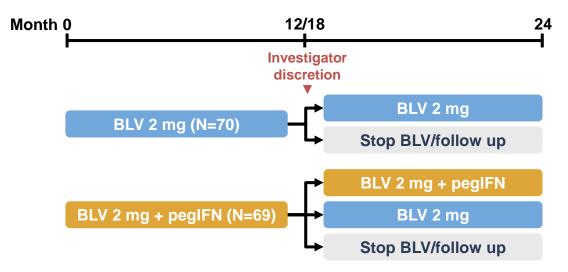
# 48-week integrated efficacy of bulevirtide monotherapy in Phase 2 and 3 trials for CHD



<sup>a</sup>Undetectable HDV RNA or 2 log decline from baseline and ALT normalization Lampertico P, et al. AASLD 2022. Poster #1024. Sponsored by Gilead Sciences, Inc.

# Real-world efficacy and safety of up to 2 years' bulevirtide treatment with or without pegIFN in HDV-infected patients enrolled in the French multicenter early access program (cATU)

- Eligibility criteria: Compensated cirrhosis or severe liver fibrosis (F3) **or** F2 fibrosis with persistent ALT>2 ULN for ≥6 months
- Multicenter, nonrandomized, open-label, observational, prospective study



### **Primary endpoint**

 Undetectable HDV RNA or ≥2 log IU/mL decrease from baseline and normal ALT (FDA criteria)

### **Secondary endpoints**

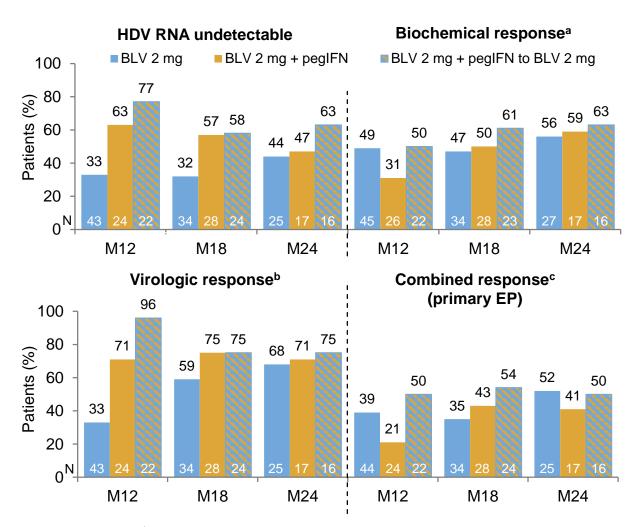
- HDV RNA undetectable from BL to Months 12, 18, and 24
- ALT normalization (<40 IU/L)</li>
- Virologic response at Months 18 and 24

#### **Baseline characteristics**

	BLV 2 mg (N=70)	BLV 2 mg + pegIFN (N=69)
Age, years	42 ±12	40 (11)
Male	50 (71)	45 (65)
Continent of birth Europe Africa	47 (67) 21 (30)	35 (52) 32 (48)
BMI, kg/m <sup>2</sup>	25.9 ±5.0	25.1 ±6.0
Cirrhosis	44 (63)	42 (61)
Liver stiffness, kPa	16.7 ±14.0	13.3 ±9
ALT, IU/mL	94 ±54	124 (97)
Median HDV RNA, log <sub>10</sub> IU/mL (IQR)	6.52 (1)	6.52 (1)
HDV DNA undetectable	46 (71)	40 (64)
HBeAg positive	6 (9)	7 (11)
Current NUC treatment	56 (80)	51 (74)
HIV infected	13 (19)	6 (9)
Data are mean ±SD or n (%) unless specif	ied	

De Ledinghen V, et al. AASLD 2022. Oral #28.

# French early access program (cATU): On-treatment responses to bulevirtide with or without pegIFN among HDV-infected patients



- BLV+PEG provides minimal-to-no benefit over BLV alone
- Still insufficient data for definition of futility rules

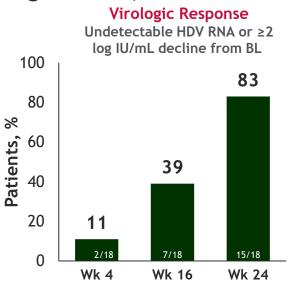
<sup>a</sup>Normalized ALT; <sup>b</sup>Undetectable HDV RNA or ≥2 log decrease from baseline; <sup>c</sup>Undetectable HDV RNA or ≥2 log decline from baseline and normal ALT De Ledinghen V, et al. AASLD 2022. Oral #28.

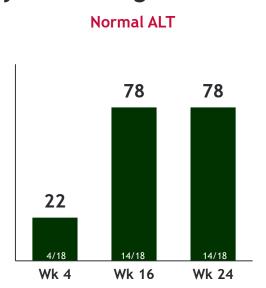


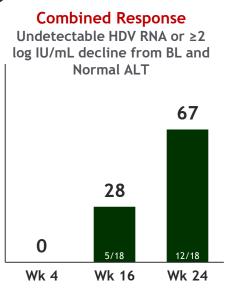
# Real World Effectiveness of BLV 2mg in HDV Patients with Advanced Cirrhosis

## Prospective, single center, real-world study of BLV 2 mg monotherapy

Characteristics	n=18
Age, years*	48 (29-77)
Male, n (%)	12 (67)
Caucasian, n (%)	18 (100)
HDV GT 1, n (%)	18 (100)
Compensated cirrhosis, n (%)	18 (100)
Child-Pugh A6, n (%)	4 (28)
CSPH features, n (%)	17 (94)
Esophageal varices, n (%)	14 (78)
Fibroscan, kPa*	16.4 (7.8-57.8)
Platelets, 10³/mmc	70 (37-227)
Active HCC, n (%)	2 (11)
Current TDF or ETV, n (%)	18 (100)
Previous IFN, %	12 (67)
ALT, U/L*	106 (32-222)
HDV RNA, log IU/mL*	4.9 (3.3-3.6)







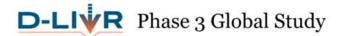
#### **Safety Profile**

No adverse events, No injection site reactions, or No BLV discontinuations No new safety signals

Real world effectiveness of BLV monotherapy in patients with clinically significant portal hypertension. BLV 2mg was well tolerated, including in patients with advanced cirrhosis, active HCC and with platelets <60,000/mmc\*\*.

CSPH=clinically significant portal hypertension.

Virologic response, HDV RNA undetectable or ≥2 log IU/mL decline from baseline. Combined response, HDV RNA undetectable or ≥2 log IU/mL decline and ALT normalization from baseline. \*median (range); \*\* 33% of patients had platelets <60,000mmc



## **D-LIVR** trial



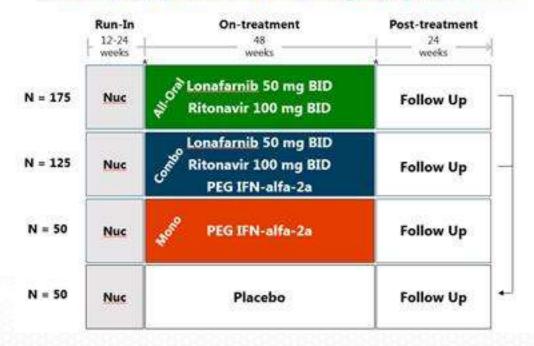
407 20+ 100+
PATIENTS COUNTRIES SITES

Topline Data Planned by End of 2022



## D-LIVR : PHASE 3 GLOBAL STUDY

### Delta-Liver Improvement and Virologic Response in HDV



#### **Primary Endpoint at Week 48**

≥ 2 log decline in HDV RNA

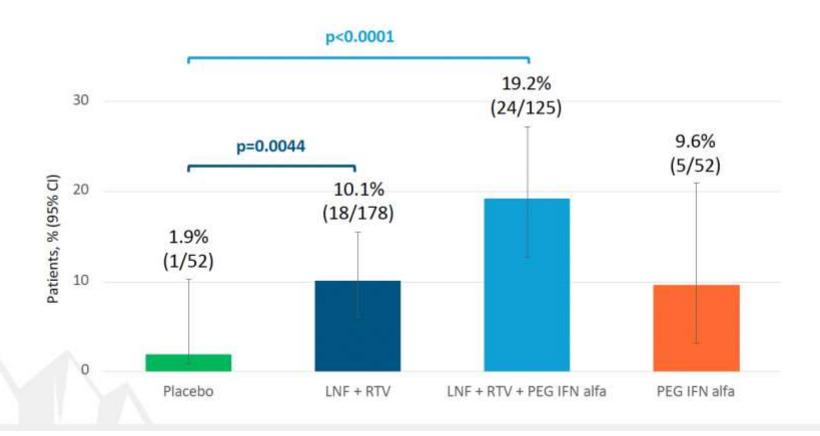
Normalization of ALT

#### Secondary Endpoint at Week 48

- Histologic improvement
  - > 2-point improvement in HAI inflammatory score
  - No progression in fibrosis
- Improvement of fibrosis

## Primary Endpoint Achieved with Significance in BOTH Arms

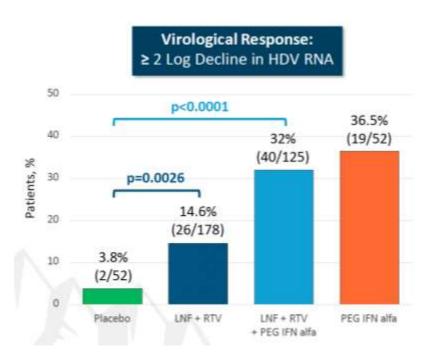
## % PATIENTS ACHIEVING COMPOSITE ≥2 LOG DECLINE IN HDV RNA + ALT NORMALIZATION AT WEEK 48

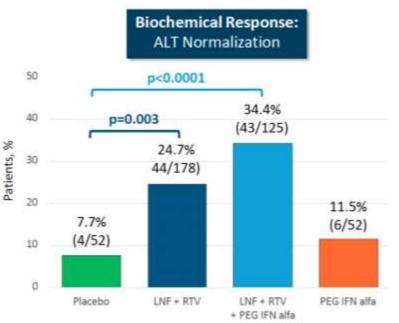


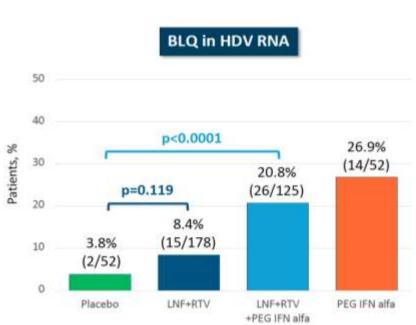


## Key Secondary Endpoints Achieved in BOTH Arms with Significance

#### COMPONENTS OF COMPOSITE PRIMARY ENDPOINT AT WEEK 48









## Histology Response Rates at Week 48

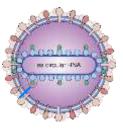
## PATIENTS WITH EVALUABLE PAIRED BIOPSIES (n=229)

	% (n)					
Response	Oral n=107	Combo n=66	PEG IFN alfa n=26	Placebo n=30		
Histologic Composite Endpoint	33% (35) (p=0.61)	53% (35) (p=0.0139)	38% (10) (p=0.46)	27% (8)		

- Histologic Composite Endpoint: ≥ 2-point improvement in HAI\* score + no worsening in Ishak fibrosis score
- Liver histology is the most direct way to assess improvements in:
  - Liver injury (necrosis and inflammation) measured by HAI score
  - Liver scarring (fibrosis) measured by fibrosis score



# Hepatitis delta: Conclusions





9-60 million people infected with HDV globally

Defective RNA virus, requiring HBV for infection

4.5-13% of HBV carriers co-infected with HDV



Most severe form of viral hepatitis

Increased risk of cirrhosis/HCC and higher mortality vs HBV

Progression to cirrhosis within 5 years and to HCC within 10 years



Eight HDV genotypes

Until recently, no approved therapeutic options

## **Take-home Points**

- HBsAg positive individuals should be screened for HDV with anti-HDV or HDV-Ag
- Anti-HDV positive patients should have HDV PCR testing
- HDV PCR positive individuals are at high risk for clinical complications and should be considered for treatment and liver cancer surveillance

# A 27 yo man with a history of HBV and IDU presents to his PCP with fatigue. He is on TdF

Labs:
AST 275
ALT 340
Tbili 0.9
HIV negative
HBsAg+, HBeAb +
HBV DNA Negative

What should you do next?

- 1. Request HDV Ab
- 2. Request HDV RNA
- 3. Order HBV Resistance panel
- 4. Switch TdF to ETV



# A 27 yo man with a history of HBV and IDU presents to his PCP with fatigue. He is on TdF

Labs:

**AST 275** 

**ALT 340** 

Tbili 0.9

HIV negative

HBsAg+, HBeAb +

**HBV DNA Negative** 

## What should you do next?

- 1. Request HDV Ab
- 2. Request HDV RNA
- 3. Order HBV Resistance panel
- 4. Switch TdF to ETV

In this individual with HBsAg and IDU he is at risk for HDV exposure. Antibody testing is the appropriate test and if positive, HDV RNA should be done. There is no reason to obtain resistance testing or to change therapy with the HBV is well controlled.



# 47 yo man with HBV/HDV coinfection presents for routine evaluation.

Labs:

ALT 22

**AST 19** 

Tbili 0.3

**CBC** normal

HBsAg+, HBeAb+

**HBV DNA** negative

HDV Ab +



## What would you recommend?

- 1. No further testing
- 2. FibroScan
- 3. RUQ US
- 4. HDV RNA

# 47 yo man with HBV/HDV coinfection presents for routine evaluation.

Labs:

ALT 22

**AST 19** 

Tbili 0.3

**CBC** normal

HBsAg+, HBeAb+

**HBV DNA negative** 

HDV Ab +

What would you recommend next?

- 1. No further testing
- 2. FibroScan
- 3. RUQ US
- 4. HDV RNA

RUQ US should be done for liver cancer screening. Although FibroScan can help determine fibrosis, it will misclassify 25% of those with HBV/HDV and would not change liver cancer screening in a man over the age of 40. HDV RNA will also inform if the HDV is active but therapy may not be indicated with normal liver enzymes.



# Thank you.

