

HEPATITIS B CLINICAL TRAINING SERIES

Management of Hepatitis B and Treatment Monitoring

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- Type the question into the chat box and Meg will read them aloud to the presenter at the end

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- **CME Grand Rounds**
- **CME Clinical Training Series**
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www.empireliverfoundation.org



The New York City Health Department Viral Hepatitis Program conducts surveillance and develops and implements programs to build capacity to prevent, manage and treat hepatitis B and C in New York City.

- **Surveillance**
- **Community Coalitions**
- **Navigation Programs**
- **Clinical Practice Facilitation**
- **Training**

www.nyc.gov/health/hepatitis

Overarching Learning Objectives

By the end of this presentation, participants will be able to:

1. Describe the importance of interprofessional collaboration in effectively meeting the healthcare, educational, and psychosocial needs of patients living with hepatitis B or C infection.
2. Describe the epidemiology of hepatitis B and C infections.
3. Describe the natural history of hepatitis B and hepatitis C infection.
4. Discuss updated guidelines to identify patients at risk for hepatitis B and/or hepatitis C infection
5. Identify appropriate antiviral treatments for people living with hepatitis B or hepatitis C
6. Explain the efficacy and safety of current and emerging therapies for hepatitis B and C
7. Summarize how to counsel patients diagnosed with hepatitis B or C

Learning Objectives

By the end of this presentation, participants will be able to:

- Describe the phases of hepatitis B (HBV) infection
- Understand who should be treated
- Review lab and imaging assessment requirements for HBV infected patients
- Discuss surveillance techniques for hepatocellular carcinoma
- Understand risk for HBV reactivation
- Recall the role of the primary care provider (PCP) in HBV care

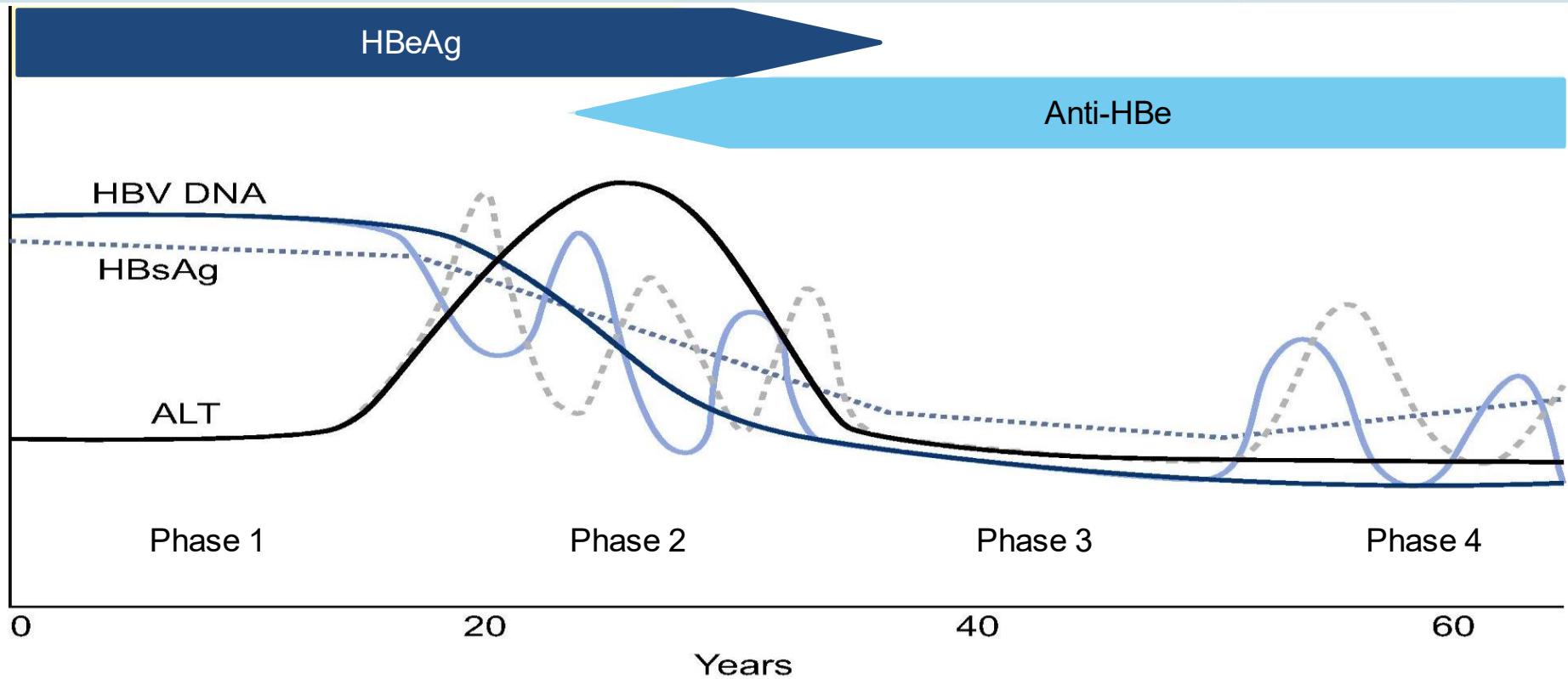


Monitoring Patients On And Off Therapy

Case Study

- 53 year-old Asian woman with HBeAg-negative hepatitis B
- ALT 22, HBV DNA PCR 302 IU/ml, HBV sAg and HBV cAb +
- Not currently on treatment
- Recently diagnosed with early stage B-cell lymphoma
- Oncologist planning to treat with a rituximab-containing regimen
- **Is there an indication for HBV treatment?**
- **Is there an indication for hepatocellular carcinoma screening?**

Phases of Chronic HBV Infection¹



Old terminology

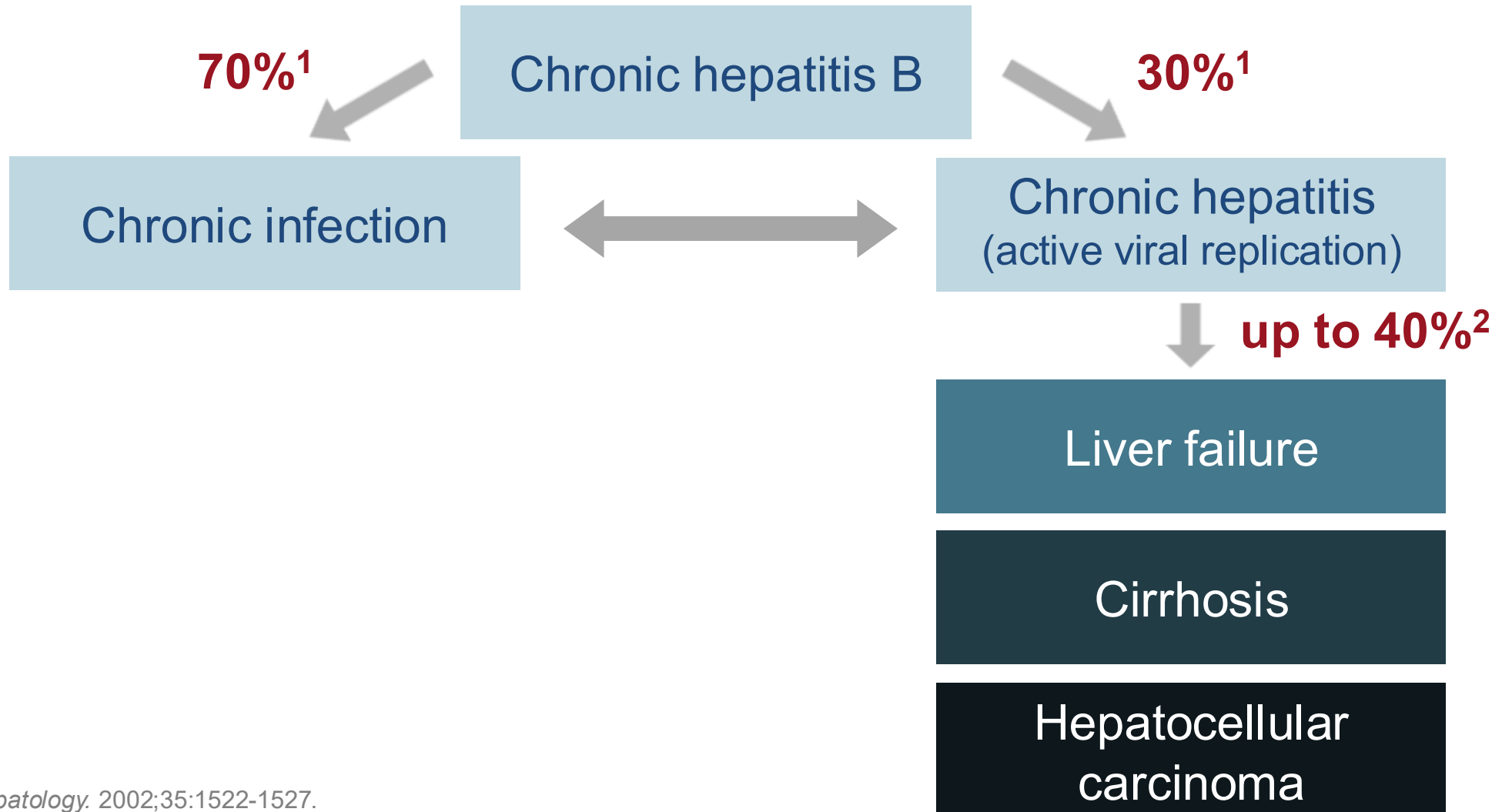
Immune tolerant Immune reactive Inactive carrier HBeAg negative chronic hepatitis

New Nomenclature²

HBeAg-positive chronic HBV infection HBeAg-positive chronic hepatitis B HBeAg-negative chronic HBV infection HBeAg-negative chronic hepatitis B

1. Lok A, et al. J Hepatol 2017;67:847-61;
 2. EASL CPG HBV. J Hepatol 2017;67:370-98

Clinical Outcome of Chronic Hepatitis B



1. Hsu YS, et al. *Hepatology*. 2002;35:1522-1527.

2. Lok AS. *N Engl J Med*. 2002;346:1682-1683.

Indications for Treatment of HBV

Treatment Not Indicated	Treatment Possibly Indicated	Treatment Indicated
<p>Immune tolerant state</p> <ul style="list-style-type: none"> Hbe-Ag detectable, high HBV DNA ($> 10^6$ IU/mL), normal ALT, age $< 30-40$ years <p>Low replicative state</p> <ul style="list-style-type: none"> Hbe-Ag undetectable, low HBV DNA (< 2000 IU/mL), normal ALT 	<ul style="list-style-type: none"> Hbe-Ag detectable, high HBV DNA ($> 10^6$ IU/mL), normal ALT, age $< 30-40$ years Presence of CP or PC mutation HBV genotype C Age $> 30-40$ years Moderate immunosuppression Extrahepatic manifestations of HBV HIV/HCV co-infection Family history of cirrhosis Personal or family history of HCC 	<ul style="list-style-type: none"> HBV DNA > 2000 IU/mL and ALT $> 2xULN$ HBV DNA > 2000 IU/mL and ALT $> ULN$, with moderate necroinflammatory activity and/or fibrosis Cirrhosis Pregnancy with HBV DNA $> 200,000$ IU/mL (begin for vertical transmission prophylaxis at 28-32 weeks gestation) Use of B-cell depleting agents or marked immunosuppression Acute HBV infection with severe liver injury (INR>2, bilirubin >3 mg/dL) or acute liver failure

Favors monitoring

Favors treatment

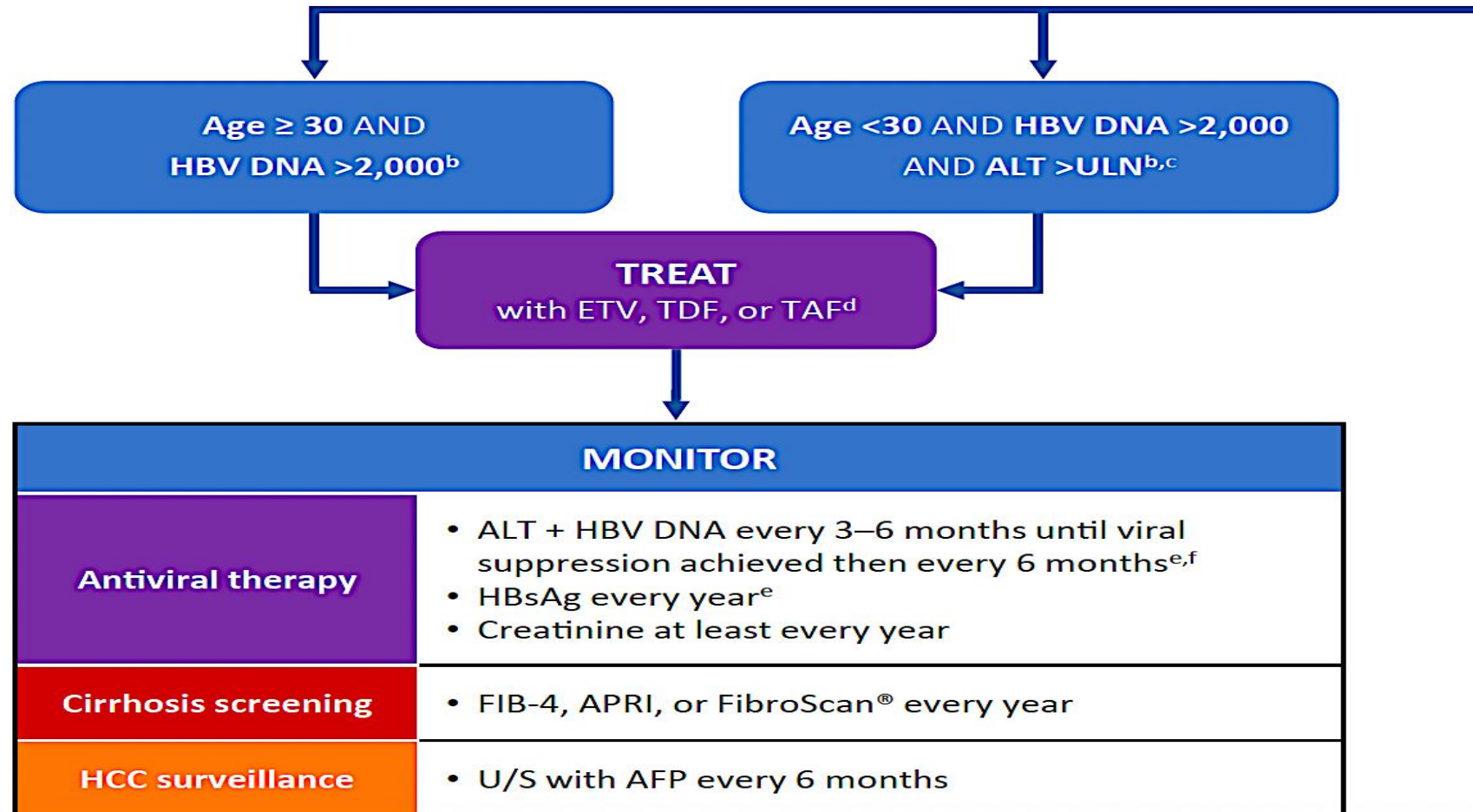
Acute HBV

Chronic HBV

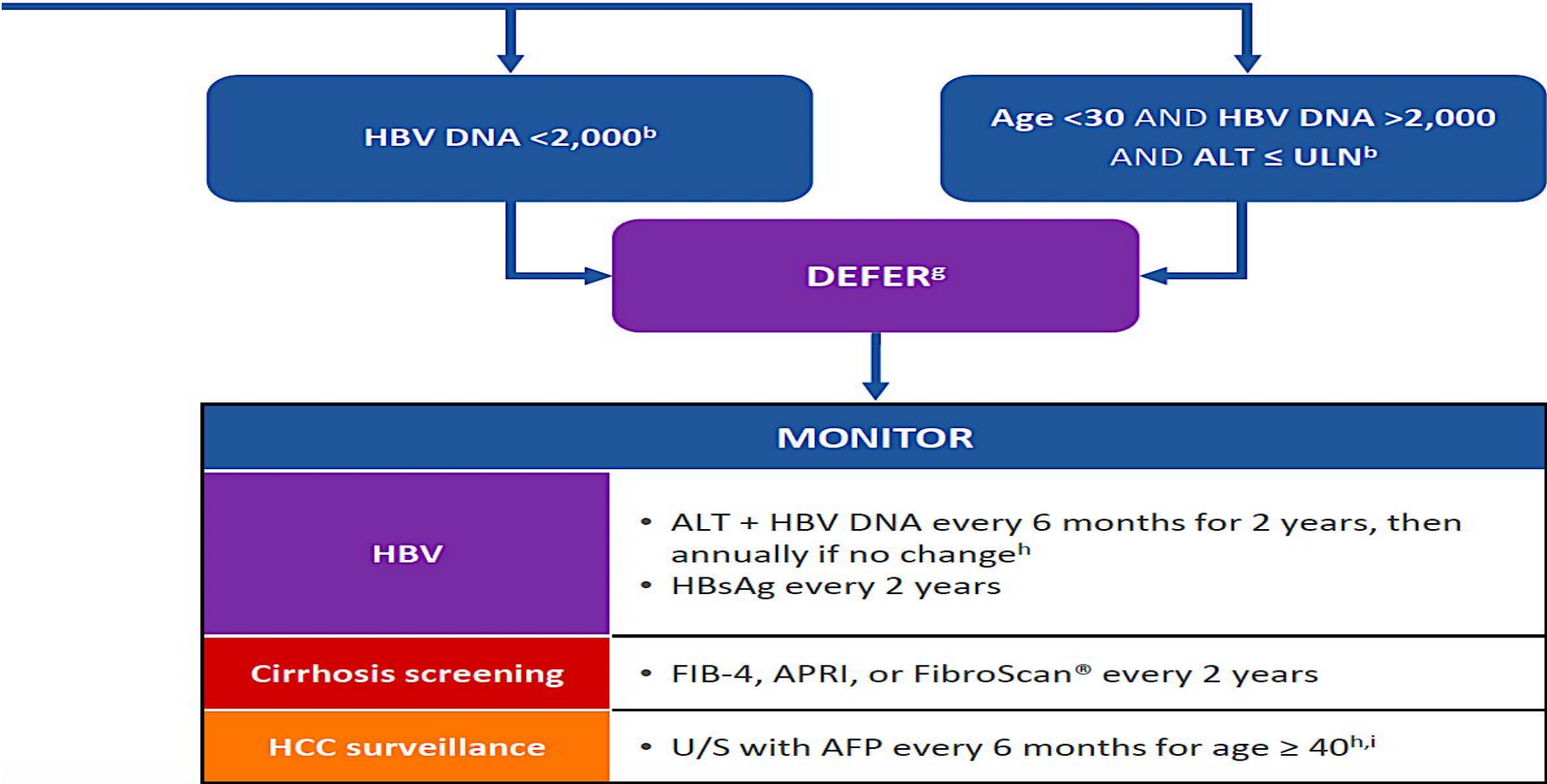
Cirrhosis

HCC

Simplified approach to HBV Elimination



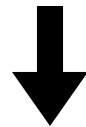
Simplified approach to HBV Elimination



Goal of HBV Therapy

Aim of treatment for chronic hepatitis B:

Achieve sustained suppression of HBV replication
(associated with normalization of ALT, loss of HBeAg, and
improvement in liver histology)



Goals of antiviral treatment:

Decrease chronic hepatitis B-related morbidity
and mortality

HBV Treatment Monitoring

Monitoring HBeAg-Positive Non-Cirrhotics on Treatment



Follow liver panel, HBV DNA every 3 months until HBV DNA undetectable


Then follow ALT, HBV DNA every 3-6 months

Check HBeAg, HBeAb and HBsAb every 6 months

If HBeAg seroconversion to HBeAb or HBsAg seroconversion to HBsAb positive, can consider stopping therapy after 12 months of consolidation

Don't forget about liver cancer screening

Monitoring HBeAg-Positive Cirrhotics on Treatment



Follow liver panel, HBV DNA every 3 months until HBV DNA undetectable

Then follow ALT, HBV DNA, BMP, INR every 3-6 months

Check HBeAg, HBeAb and HBsAb every 6 months

If HBeAg seroconversion to HBeAb occurs, stopping therapy is not advised

If HBsAg seroconversion to HBsAb occurs, stopping therapy can be considered after 12 months of consolidation

Don't forget about liver cancer screening

Monitoring HBeAg-Negative Non-Cirrhotics on Treatment



Follow liver panel, HBV DNA every 3 months until HBV DNA undetectable


Then follow liver panel, HBV DNA every 3-6 months

Check HBsAg and HBsAb every 6 months

If HBsAg seroconversion to HBsAb positive, consider stopping therapy after 12 months of consolidation

Don't forget about liver cancer screening

Monitoring HBeAg-Negative Cirrhotics on Treatment



Follow ALT, HBV DNA every 3 months until HBV DNA undetectable

Then follow liver panel, BMP, HBV DNA every 3-6 months

Check HBsAg and HBsAb every 6 months

If HBsAg seroconversion to HBsAb positive, consider stopping therapy after 12 months of consolidation

Don't forget about liver cancer screening

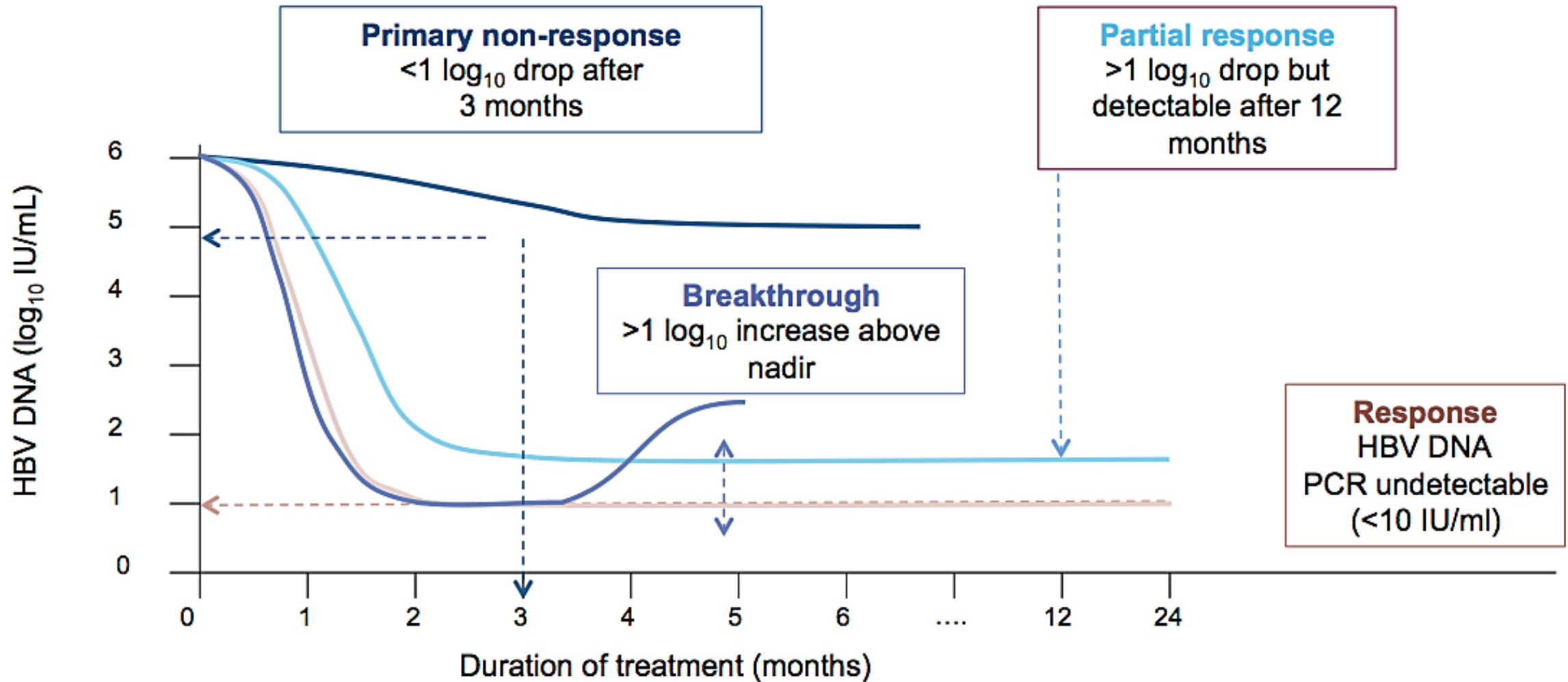
Persistent Viremia

- Defined as detectable HBV DNA after 96 weeks of treatment
- Ensure patient compliance
- Insufficient evidence to recommend switching to an alternate medication or adding an additional one
- If viral levels low, resistance likely not a concern
- Consider testing for HBV resistance if the patient is on low dose entecavir (0.5 mg daily)

Viral Breakthrough

- Defined as increase in HBV DNA by > 1 log compared to nadir or HBV DNA ≥ 100 IU/ml in a patient with previously undetectable DNA on therapy
- Confirm with repeat testing prior to making changes
- Resistance testing can assist with decisions
- General strategy:
 - Switch entecavir to tenofovir
 - Add entecavir to tenofovir or switch to tenofovir + emtricitabine combination

Virological Responses on NA Therapy



When Can HBV Therapy Be Stopped?

Criteria for Stopping NA Therapy

	AASLD 2016	APASL 2016	EASL 2017
HBeAg+, no cirrhosis	HBeAg seroconversion & UD HBV DNA + ≥ 12 months consolidation	HBeAg seroconversion & UD HBV DNA plus preferably 3 years consolidation	HBeAg seroconversion & UD HBV DNA plus ≥ 12 months consolidation
HBeAg-, no cirrhosis	HBsAg loss?	HBsAg loss + anti-HBs seroconversion or ≥ 12 months consolidation or after >2 year treatment with 3 UD HBV DNA >6 months apart	HBsAg loss or in selected patients after ≥ 3 years UD HBV DNA & available for close follow-up
Cirrhosis, HBeAg+ or HBeAg-	DO NOT STOP	May be considered with careful off-therapy monitoring plan	DO NOT STOP

UD=undetectable

Terrault NA, *Hepatology* 2016; 63: 261; Sarin SK, *Hepatol Int* 2016; 10: 1; EASL, *J Hepatol* 2017; 67: 370

HBV Therapy “Drug Holiday”

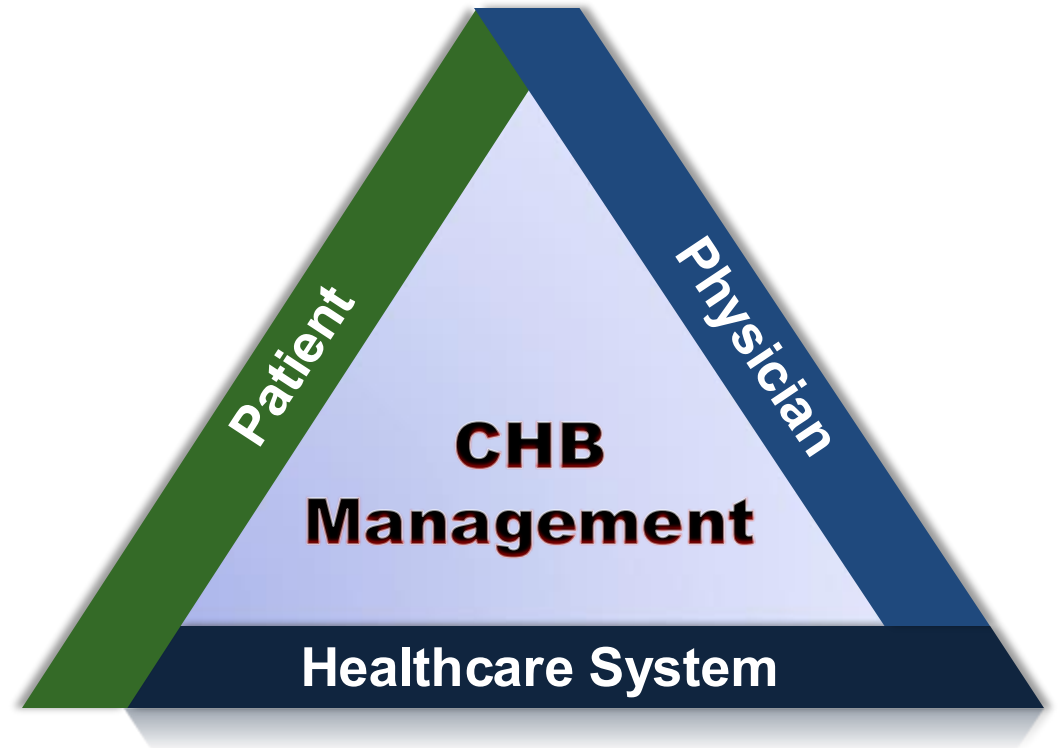
- There is no such thing as a drug holiday from HBV medications
- In a patient who takes a “drug holiday”:
 - Check baseline HBV parameters
 - ALT, e Ag status, HBV-DNA
 - Restart same HBV therapy
 - Repeat parameters in 3 months

Monitoring of Patients Who Have Discontinued HBV Therapy

- ALT and HBV-DNA testing every 3-6 months
- Abdominal sonogram + AFP every 6 months
- Restart HBV therapy according to accepted treatment parameters
- No further monitoring if HBsAg seroconversion and no evidence of cirrhosis

Factors Influencing CHB Management

- Many factors play a role in influencing adherence to monitoring recommendations and CHB management plans^{1,2}
- Physicians and patients can work together within the healthcare system to overcome these challenges



Factors Limiting Patient Adherence With CHB Management Plans

- ✓ Limited knowledge about CHB^{1,2}
- ✓ Lack of symptoms²
- ✓ English as a second language³
- ✓ Financial barriers⁴
- ✓ Cultural beliefs⁴⁻⁶

Barriers to Patient Adherence: Limited Patient-Physician Communication

Areas where physicians may have limited communication with patients:

General areas

- Patient lifestyle
- Assessing patients' willingness to start therapy
- CHB disease state
- Rationale for physician recommendations
- Objectives/end goals of management

Treatment-related areas

- Benefits and side effects of therapy
- Cost of medication
- Difficulties during treatment course

Monitoring Patients Currently Not Treated

HBeAg-positive chronic HBV infection

- Age < 30 years
- Not meeting routine treatment criteria



Follow every 3-6 months

HBeAg-negative chronic HBV infection

- HBV DNA < 2000 IU/mL
- Not meeting routine treatment criteria



Follow every 3-6 months

HBeAg-negative chronic HBV infection

- HBV DNA \geq 2000 IU/mL
- Not meeting routine treatment criteria



Follow every 3 months for 1 year. Then, every 6 months.

Typical tests

- ALT every 3-6 mo.
- HBV DNA every 6-12 months.
- Reassess liver fibrosis every 12 months
- Don't forget about liver cancer screening

Hepatocellular Carcinoma (HCC) Surveillance

Hepatocellular Carcinoma (HCC) Surveillance

- Non-cirrhotic HBV is a risk factor for HCC
- HBV is oncogenic
 - Likely related to DNA integration into host genome and insertional mutagenesis of cancer-related genes
- Threshold for screening in HBV without cirrhosis occurs when the **annual incidence $\geq 0.2\%$**
 - Considered cost-effectiveness relative to life years gained

AASLD Guidelines: HCC Screening in Non-Cirrhotic HBV

- HBV carriers at high risk for HCC, include:
 - HBsAg positive patients with cirrhosis
 - Asian or Black men over 40 years and Asian women over 50 years of age
 - Family history of HCC- first degree
 - HDV infection
 - Any carrier over 40 years with persistent or intermittent ALT elevation and/or high HBV DNA level >2,000 IU/mL
- Screening is with ultrasound examination every 6 months.

Cirrhosis: AASLD 2017 Guidelines

- 1A. AASLD recommends surveillance of adults with cirrhosis because it improves overall survival.
- 1B. AASLD suggests surveillance using ultrasound (US), with or without alphafetoprotein (AFP), every 6 months.
- 1C. AASLD suggests not performing surveillance of patients with cirrhosis with Child's class C unless they are on the transplant waiting list, given the low anticipated survival for patients with Child's C cirrhosis.

Cirrhosis: AASLD 2017 Guidelines

2. The AASLD recommends diagnostic evaluation for HCC with either multiphasic CT or multiphasic MRI because of similar diagnostic performance characteristics

Technical Remarks

1. The selection of the optimal modality and contrast agent for a particular patient depends on multiple factors beyond diagnostic accuracy. These include modality availability, scan time, throughput, scheduling backlog, institutional technical capability, exam costs and charges, radiologist expertise, patient preference, and safety considerations.
2. All studies were performed at academic centers. Because of the greater technical complexity of multiphasic MRI compared to multiphasic CT, generalizability to practices without liver MRI expertise is not yet established.

LI-RADS (American College of Radiology)

CATEGORIES

LR-1	Definitely Benign	Concept: 100% certainty observation is benign. Definition: Observation with imaging features diagnostic of a benign entity, or definite disappearance at follow up in absence of treatment.
LR-2	Probably Benign	Concept: High probability observation is benign. Definition: Observation with imaging features suggestive but not diagnostic of a benign entity.
LR-3	Intermediate probability for HCC	Concept: Both HCC and benign entity have moderate probability. Definition: Observation that does not meet criteria for other LI-RADS categories.
LR-4	Probably HCC	Concept: High probability observation is HCC but there is not 100% certainty. Definition: Observation with imaging features suggestive but not diagnostic of HCC.
LR-5	Definitely HCC	Concept: 100% certainty observation is HCC. Definition: Observation with imaging features diagnostic of HCC or proven to be HCC at histology.
LR-5V	Definitely HCC with Tumor In Vein	Concept: 100% certainty observation is HCC invading vein. Definition: Observation with imaging features diagnostic of HCC invading vein.
LR-M	Probably Malignant, not specific for HCC	Concept: Observation is probably malignant, but imaging features are not specific for HCC. Definition: Observation with imaging features suggestive of non-HCC malignancy.
LR-Treated	Treated Observation	Concept: A loco-regionally treated observation. Definition: Observation of any category that has undergone loco-regional treatment.

Typical HCC Radiographic Appearance

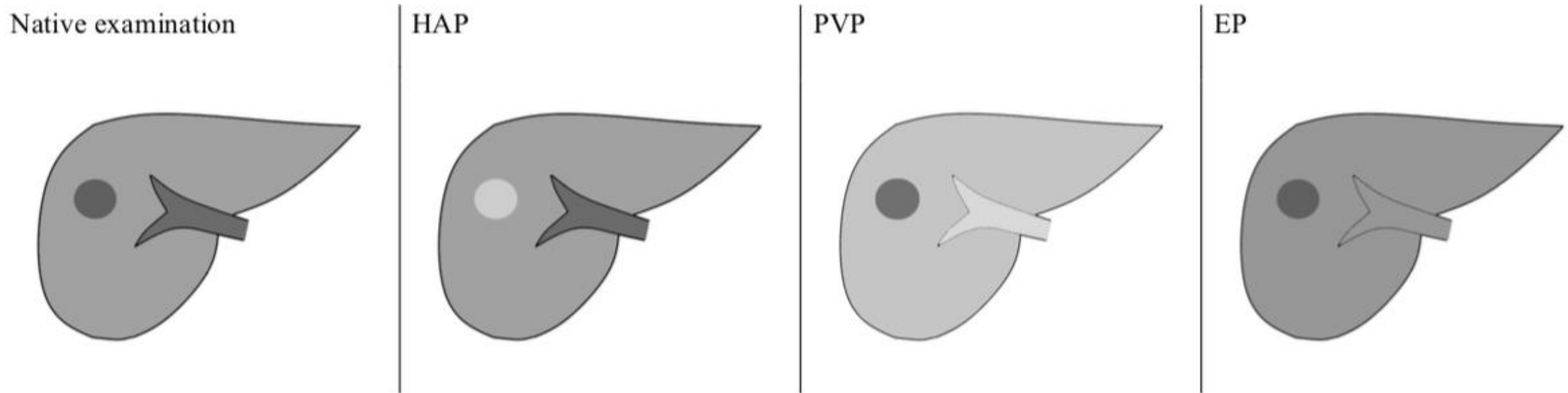


Fig. (12). Schematic presentation of pattern of enhancement of HCC lesion with strong enhancement in HAP (bright, hyperdense lesion in comparison to surrounding liver parenchyma) and wash-out of contrast agent in subsequent PVP and EP (dark, hypodense lesion).

HAP - hepatic arterial phase, EP - equilibrium phase, PVP - portal venous phase.

Alpha-Fetoprotein (AFP): Send or Not?

- Produced by approximately 70% of HCCs
- Can also be elevated by active hepatitis and from non-liver causes (pregnancy, germ cell tumor)
- Insufficient evidence to determine whether imaging + AFP is superior to imaging alone for screening
- Can be useful adjunct to imaging
- Cannot replace imaging as screening (30% HCCs do not produce AFP)

Chronic HBV: Other Concerns

- Vaccination for HAV if not immune
- Counseling on risk of transmission to sexual partners/household contacts
- Upper endoscopy for varices screening in cirrhotics
- Risk of flare and/or antiviral resistance with discontinuation of therapy



Prevention of HBV Reactivation During Immunosuppressive Drug Therapy

Monitoring HBV-Exposed Patients on Immunosuppression: Treat Prophylactically?

■ High-risk (>10%)

■ Moderate-risk (1-10%)

■ Low-risk (<1%)

	HBsAg+/ HBcAb+	HBsAg-/ HBcAb+
B cell-depleting agents (eg, rituximab, ofatumumab)	High-risk (>10%)	High-risk (>10%)
Anthracycline derivatives (eg, doxorubicin, epirubicin)	High-risk (>10%)	Moderate-risk (1-10%)
High-dose (> 20 mg prednisone daily or equivalent) corticosteroids daily for ≥ 4 weeks	High-risk (>10%)	Moderate-risk (1-10%)
Moderate-dose (10–20 mg prednisone daily or equivalent) corticosteroids daily for ≥ 4 weeks	High-risk (>10%)	Moderate-risk (1-10%)
TNF alpha inhibitors (eg, etanercept, adalimumab, certolizumab, infliximab)	Moderate-risk (1-10%)	Moderate-risk (1-10%)
Cytokine or integrin inhibitors (eg, abatacept, ustekinumab, natalizumab, vedolizumab)	Moderate-risk (1-10%)	Moderate-risk (1-10%)
Tyrosine kinase inhibitors (eg, imatinib, nilotinib)	Moderate-risk (1-10%)	Moderate-risk (1-10%)
Low-dose (< 10 mg prednisone daily or equivalent) corticosteroids for duration of ≥ 4 weeks	Moderate-risk (1-10%)	Low-risk (<1%)
Any dose of oral corticosteroids daily for ≤ 1 week	Low-risk (<1%)	Low-risk (<1%)
Intra-articular corticosteroids	Low-risk (<1%)	Low-risk (<1%)
Traditional immunosuppressive agents (eg, azathioprine, 6-mercaptopurine, methotrexate)	Low-risk (<1%)	Low-risk (<1%)

HBVR, HEPATITIS B VIRUS REACTIVATION; HBCAB+, ANTI-HBC-POSITIVE
 REDDY KR, ET AL. *GASTROENTEROLOGY*. 2015;148:215–219.

AGA Guideline on Prophylaxis of HBV Reactivation During Immunosuppressive Drug Therapy

	High-Risk	Moderate-Risk	Low-Risk
Anticipated incidence of HBVr	> 10%	1 – 10%	< 1%
AGA Recommendation	Antiviral prophylaxis during IS & for at least 6–12 months after D/C of IS therapy	Antiviral prophylaxis during IS & for at least 6 months after D/C of IS therapy	No antiviral prophylaxis

- AGA suggests to use antiviral drugs with a high barrier to resistance
- No recommendation for a strategy of HBV DNA monitoring followed by rescue therapy as an alternative to antiviral prophylaxis

HBVR, hepatitis B virus reactivation; HBCAB+, Anti-HBc-positive

High-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with B cell-depleting agents, or HBsAg+/HBcAb+ treated with anthracycline derivatives, moderate- or high-dose corticosteroids daily for ≥ 4 weeks

Moderate-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with TNF alpha inhibitors, other cytokine or integrin inhibitors, tyrosine kinase inhibitors, HBsAg+/HBcAb+ treated with low-dose corticosteroids for duration of ≥ 4 weeks, HBsAg-/HBcAb+ treated with moderate- or high-dose corticosteroids daily for ≥ 4 weeks or anthracycline derivatives

Low-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with traditional immunosuppressive agents, intra-articular corticosteroids, any dose of oral corticosteroids daily for ≤ 1 week, or HBsAg-/HBcAb+ treated with low-dose corticosteroids for ≥ 4 weeks

AGA Guideline on Screening for HBV Before Starting Immunosuppressive Drug Therapy

	High-Risk	Moderate-Risk	Low-Risk
Anticipated incidence of HBVr	> 10%	1 – 10%	< 1%
AGA Recommendation	Recommend screening	Recommend screening	Recommend against screening

Screening should include HBsAg and HBcAb, followed by a sensitive HBV DNA if positive

HBVr, hepatitis B virus reactivation; HBCAB+, Anti-HBc-positive

High-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with B cell-depleting agents, or HBsAg+/HBcAb+ treated with anthracycline derivatives, moderate- or high-dose corticosteroids daily for ≥ 4 weeks

Moderate-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with TNF alpha inhibitors, other cytokine or integrin inhibitors, tyrosine kinase inhibitors, HBsAg+/HBcAb+ treated with low-dose corticosteroids for duration of ≥ 4 weeks, HBsAg-/HBcAb+ treated with moderate- or high-dose corticosteroids daily for ≥ 4 weeks or anthracycline derivatives

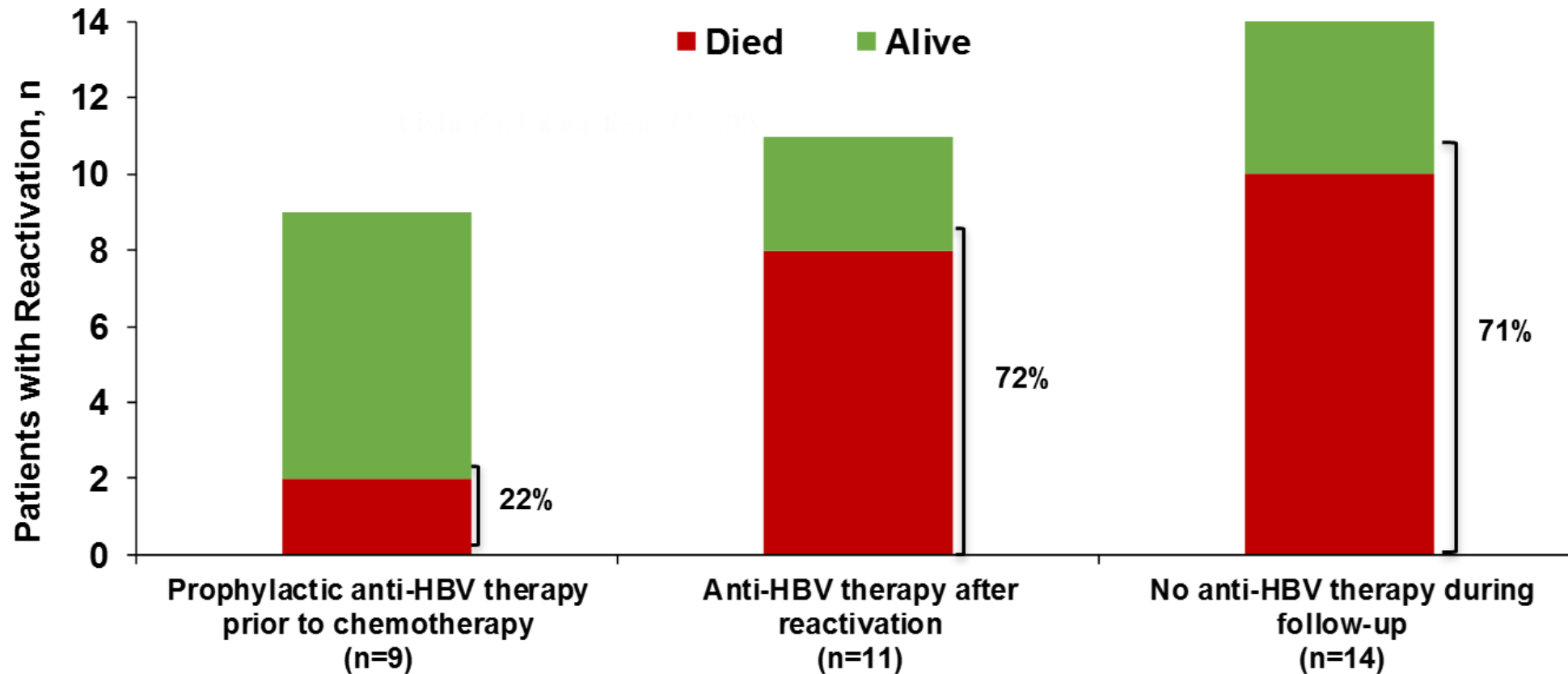
Low-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with traditional immunosuppressive agents, intra-articular corticosteroids, any dose of oral corticosteroids daily for ≤ 1 week, or HBsAg-/HBcAb+ treated with low-dose corticosteroids for ≥ 4 weeks

EASL Guidelines: Patients Undergoing Immunosuppressive Therapy Or Chemotherapy

Recommendations:

- **All candidates** for chemotherapy and immunosuppressive therapy should be tested for HBV markers prior to immunosuppression
- **All HBsAg-positive** patients should receive ETV, TDF, or TAF as treatment or prophylaxis
- **HBsAg-negative, HBcAb-positive** subjects should receive anti-HBV prophylaxis if they are at high risk of HBV reactivation

Prophylaxis Reduced Mortality in Patients With HBV Reactivation



Case Study

- 53 year-old Asian woman with HBeAg-negative Hepatitis B, HBV S Ag and HBV C Ab +
- No cirrhosis
- ALT 22, HBV DNA PCR 302 IU/ml
- Not currently on treatment
- Recently diagnosed with early stage B-cell lymphoma
- Oncologist planning to treat with a rituximab-containing regimen
- **Is there an indication for HBV treatment?**
- **Is there an indication for hepatocellular carcinoma screening?**

Case Study

- **Yes, there is an indication for prophylactic HBV therapy**
 - B-cell depleting agent + HBsAg positive is > 10% (high) risk
 - Start entecavir or tenofovir
 - Continue for at least 6-12 months after chemotherapy completed
- **Yes, she should be screened for HCC**
 - Non-cirrhotic Asian woman > 50 years old
 - Ultrasound +/- AFP every 6-12 months

Summary

- Lab monitoring on therapy depends on HBeAg status and presence or absence of cirrhosis
- Viral breakthrough is a concern and is usually related to noncompliance or viral resistance
- HCC screening should be performed in all cirrhotic patients and noncirrhotic HBV patients who meet criteria
- Certain immunosuppressive medications place patients at significant risk of HBV reactivation if not treated with antiviral prophylaxis

Hepatitis B Treatment Guidelines and Resources

- Treatment Guidelines - [AASLD](#)
- Drug-Drug Interactions - <https://www.hep-druginteractions.org/>

Hepatitis B Resources

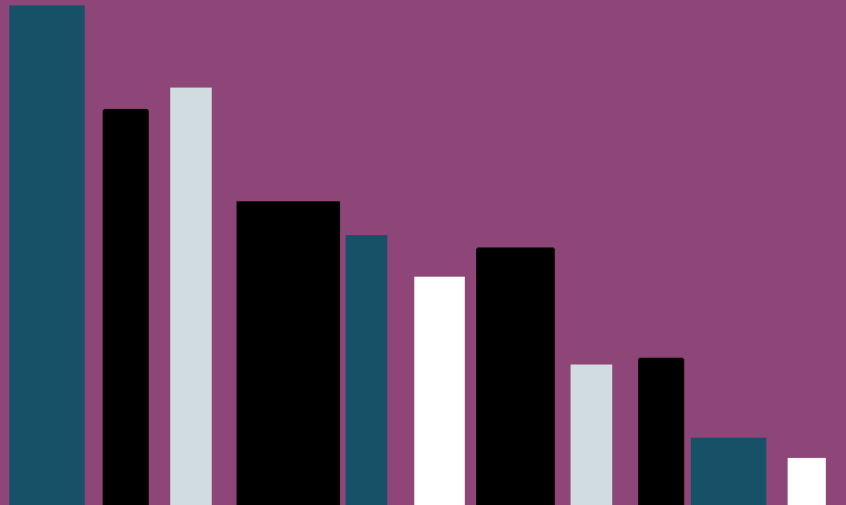
- www.HepFree.NYC
 - [Hep B Coalition](#)
 - [Clinical Resources](#)
 - [Capacity building tools](#)
 - [Advocacy Committee](#)
- Hepatitis B patient information page: www.nyc.gov/health/hepb
 - Free or low-cost testing and treatment

Elimination Plan and Annual Report

Plan to

Eliminate Viral Hepatitis

as a Major Public Health Threat
in New York City
by 2030




The bar chart consists of 11 vertical bars of varying heights and colors. From left to right, the bars are: a tall teal bar, a black bar, a light blue bar, a black bar, a teal bar, a white bar, a black bar, a light blue bar, a black bar, a teal bar, and a white bar. The heights of the bars generally decrease from left to right, with some fluctuations.

Working Toward a

Hep Free NYC

2023 Hepatitis A, B and C in NYC Report



The illustration shows a suspension bridge with two tall towers and numerous cables. The bridge is rendered in white line art against a blue background. The bridge spans across the bottom of the page, with the towers rising towards the top.

Contact Us

For CMEs or educational opportunities, contact:

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