




SPLIT
Society of Pediatric Liver Transplantation

Texas Children's Hospital®

Baylor College of Medicine

Viral Hepatitis B and C

4th Year Transplant Hepatology Fellows Lecture Series

Daniel H. Leung, MD, FAASLD
Associate Professor of Pediatrics
Director of Hepatology and Liver Transplant Medicine

Pediatrics

Disclosures

In the past 12 months, I have had the following relevant financial relationships with the following manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services:

Grant/Research Support: Abbvie, Gilead, Mirum, CF Foundation

Medical Advisory: Merck, Gilead

-Use of trade or brand names to ensure familiarity with DAA's only

Objectives

- To review the epidemiology, risk factors, and clinical presentation of hepatitis B and C
- To understand hepatitis serologies in a variety of settings and importance of PCR testing
- To become familiar with the standard of care therapeutics for HBV and HCV
- To identify barriers to access to direct acting antivirals (DAA's) for HCV in pediatrics

Hepatitis B

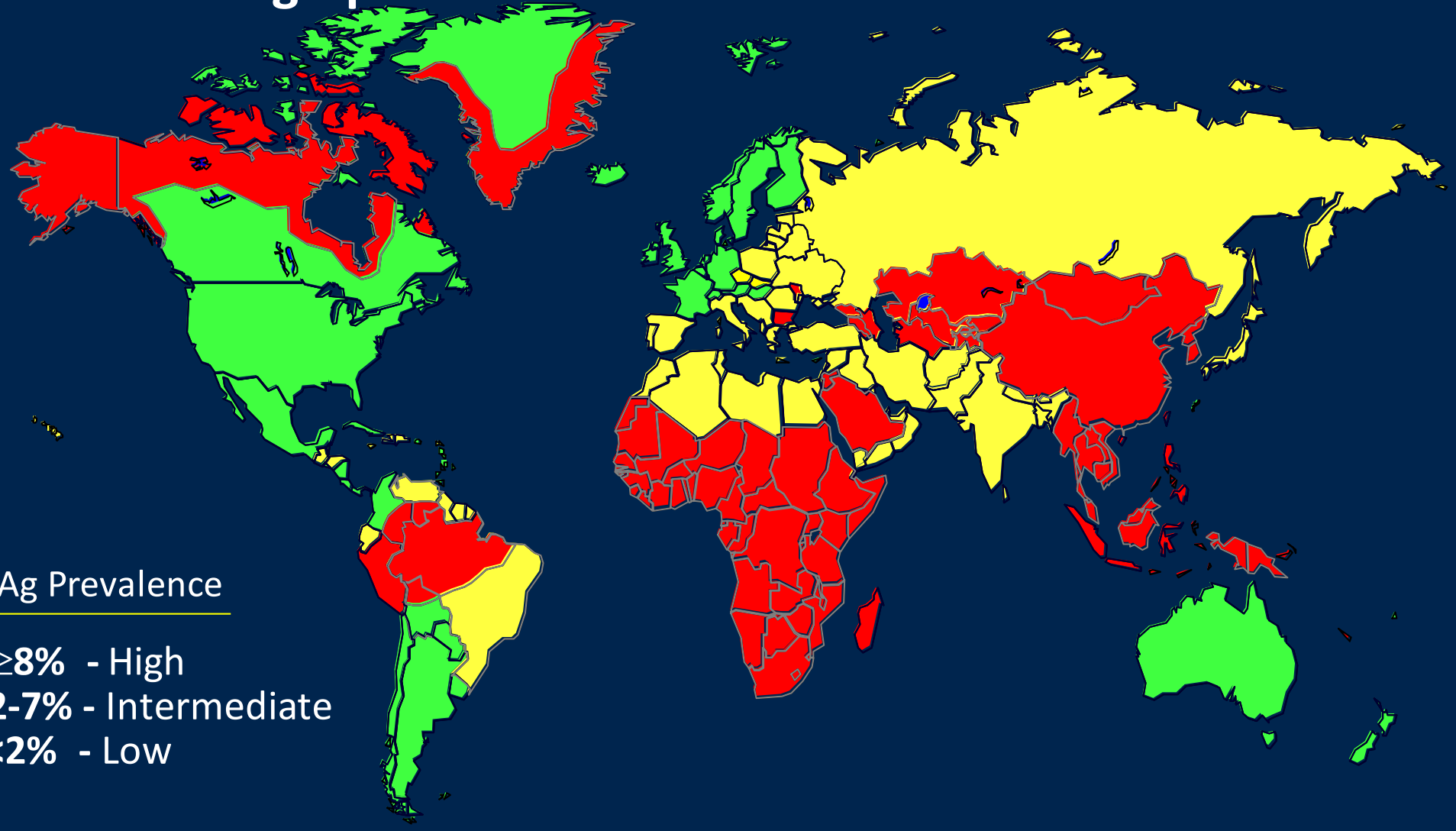
- Major Global Health Problem

  -400 million carriers worldwide

  -1.8 million chronically infected in the U.S.
  - Defined as surface antigen for > 6 months
  - 6 main genotypes, A-F
  - 20% will develop cirrhosis

  -1/3 of chronic HBV infections in the U.S. start in early childhood

Geographic Distribution of Chronic HBV Infection

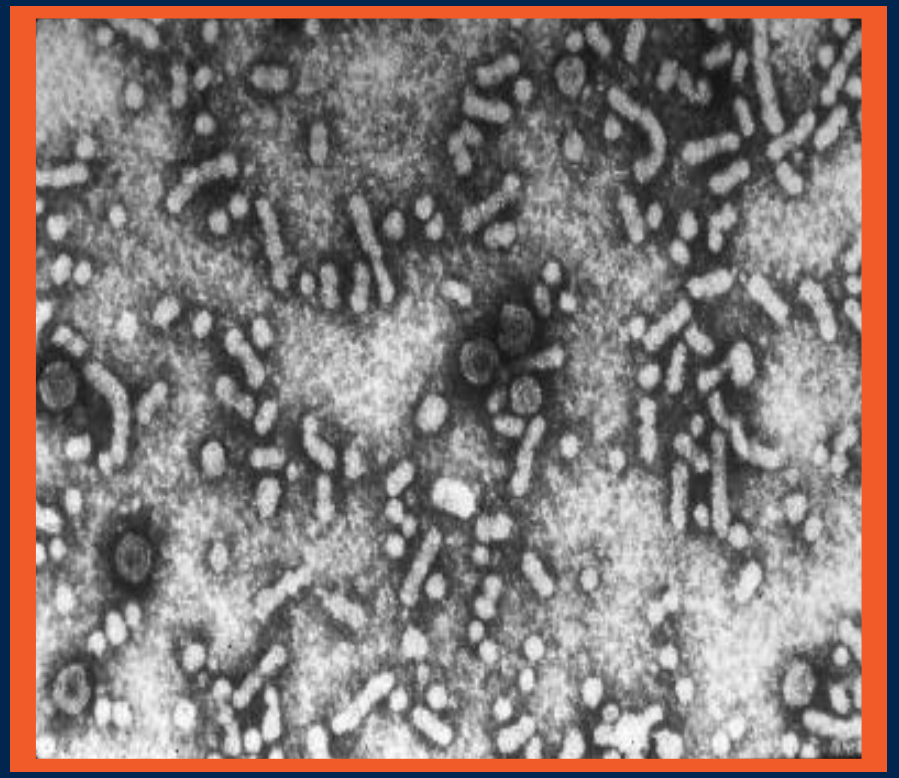


Texas Children's Hospital®

Baylor College of Medicine®

Hepatitis B Mortality

- Behind flu and pneumococcus, HBV claims more lives than any other vaccine-preventable disease (VPD). Close to 1 million/yr
- HBV is 100x more infectious than HIV
- 500,000 deaths/yr from liver cancer



Vertical Transmission

- Increased when mother is e Ag positive
  - -90% chance
  - -20% risk if mom is e Ag negative
- Maternal acute hep B in 3rd trimester
- EAb moms without measurable virus?

Infants

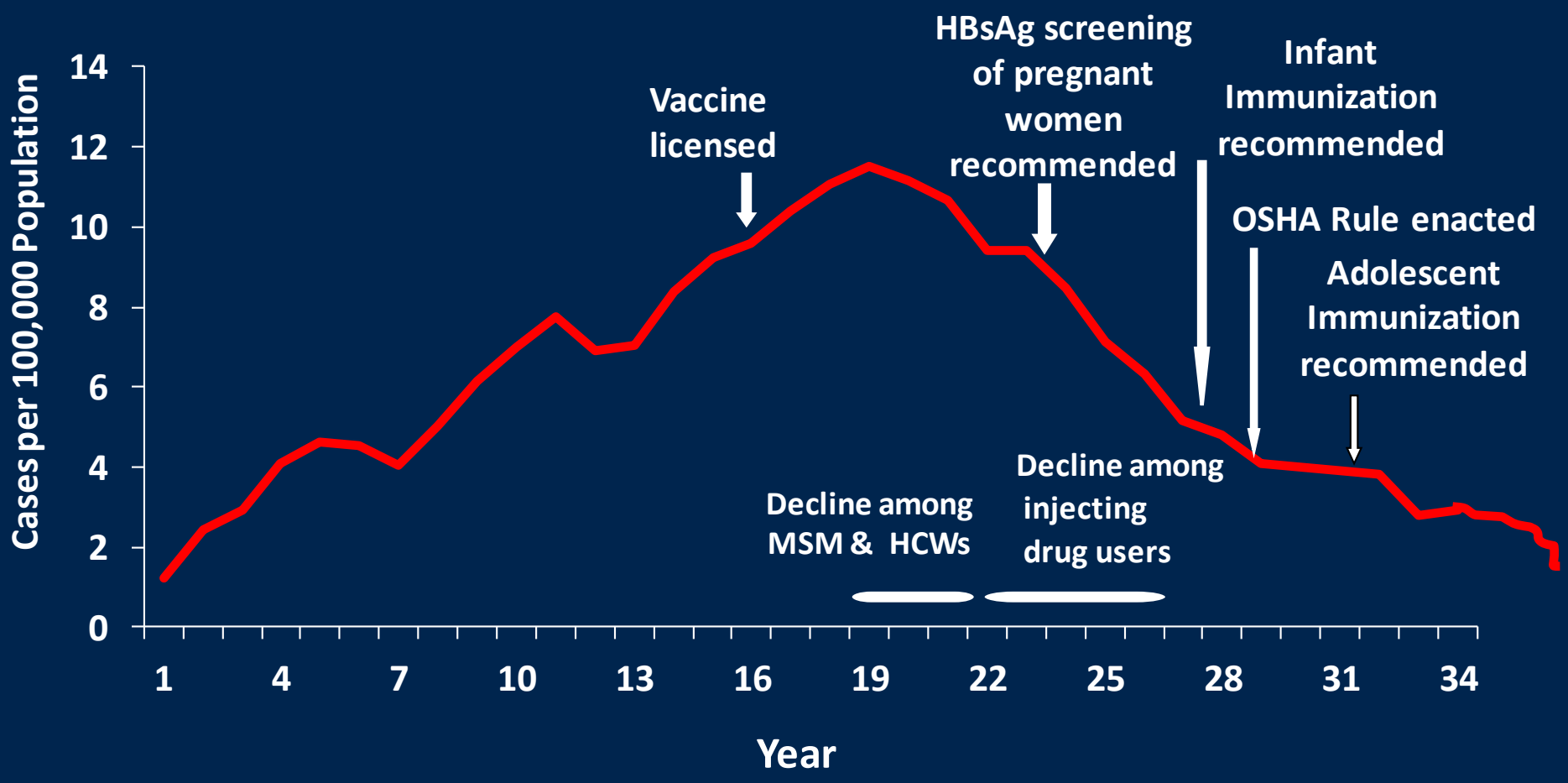
- HBIG in delivery room or within 12 hours of birth
- Vaccine at birth, 2nd dose at first well check (1-2 months of age), 3rd dose at 6 months
- HBIG alone only 75% effective, vaccine at birth improves vaccination rate

Elimination of HBV Transmission, United States

Strategy

- Prevent perinatal transmission
- Routine vaccination of all infants
- Vaccination of children in high-risk groups
- Vaccination of all children to age 18
- Vaccination of adults in high-risk groups

Hepatitis B by Year, United States, 1966 - Current



Texas Children's Hospital®

Baylor College of Medicine

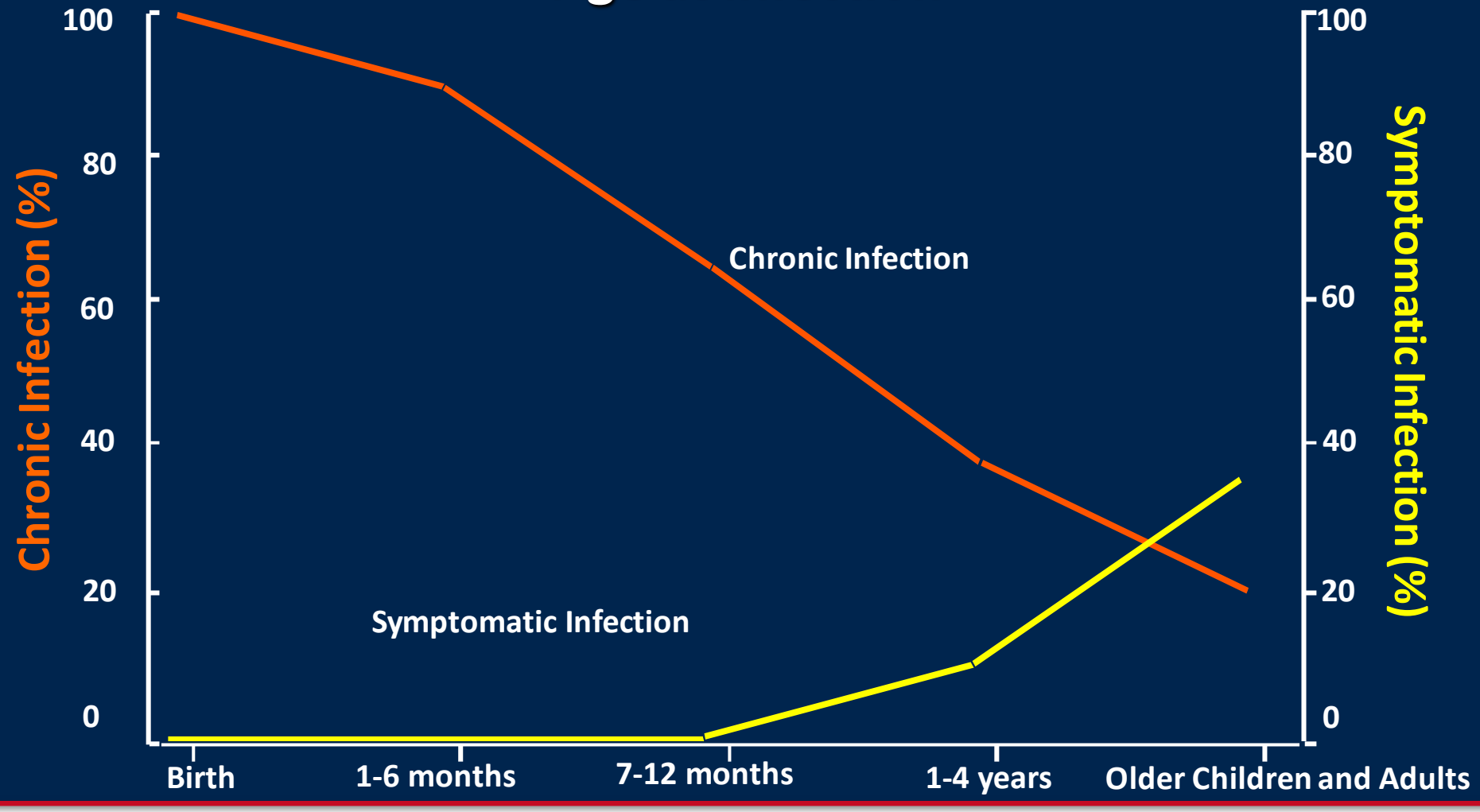
Horizontal Transmission
Concentration of Hep B in Body Fluids

High	Moderate	Low Undetectable
blood	semen	urine
serum	vaginal fluid	feces
wound exudates	saliva	sweat
		tears
		breastmilk

Differences in Pediatric Hep B

- Children are less likely to clear hepatitis B
- Only 5% of newborns that acquire the infection from their mother at birth will clear
- Children are rarely symptomatic!

Outcome of Hepatitis B Virus Infection by Age at Infection



What about those Ag's and Ab's?

HBsAg: 1st to appear
- Acute or chronic infection

HBeAg: Use to monitor success of treatment
- Active viral replication in liver

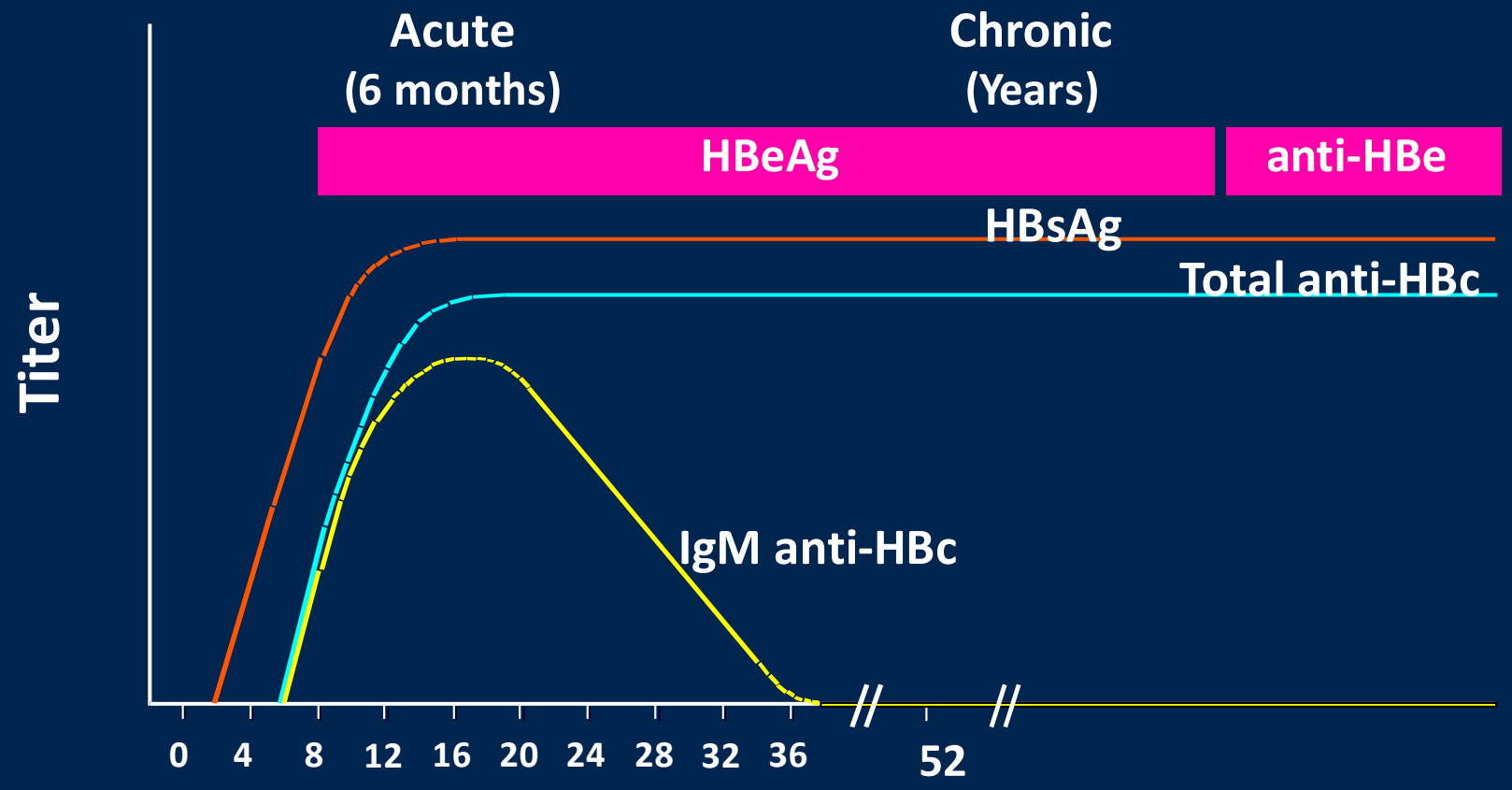
HBsAb: Last to appear
- Recovery of acute infection or history of immunization

HBcAb: Lifelong
- History of past infection

HBeAb: Gold standard of "cure"
- Immune clearance and pending seroconversion

HBV DNA quantitative PCR testing

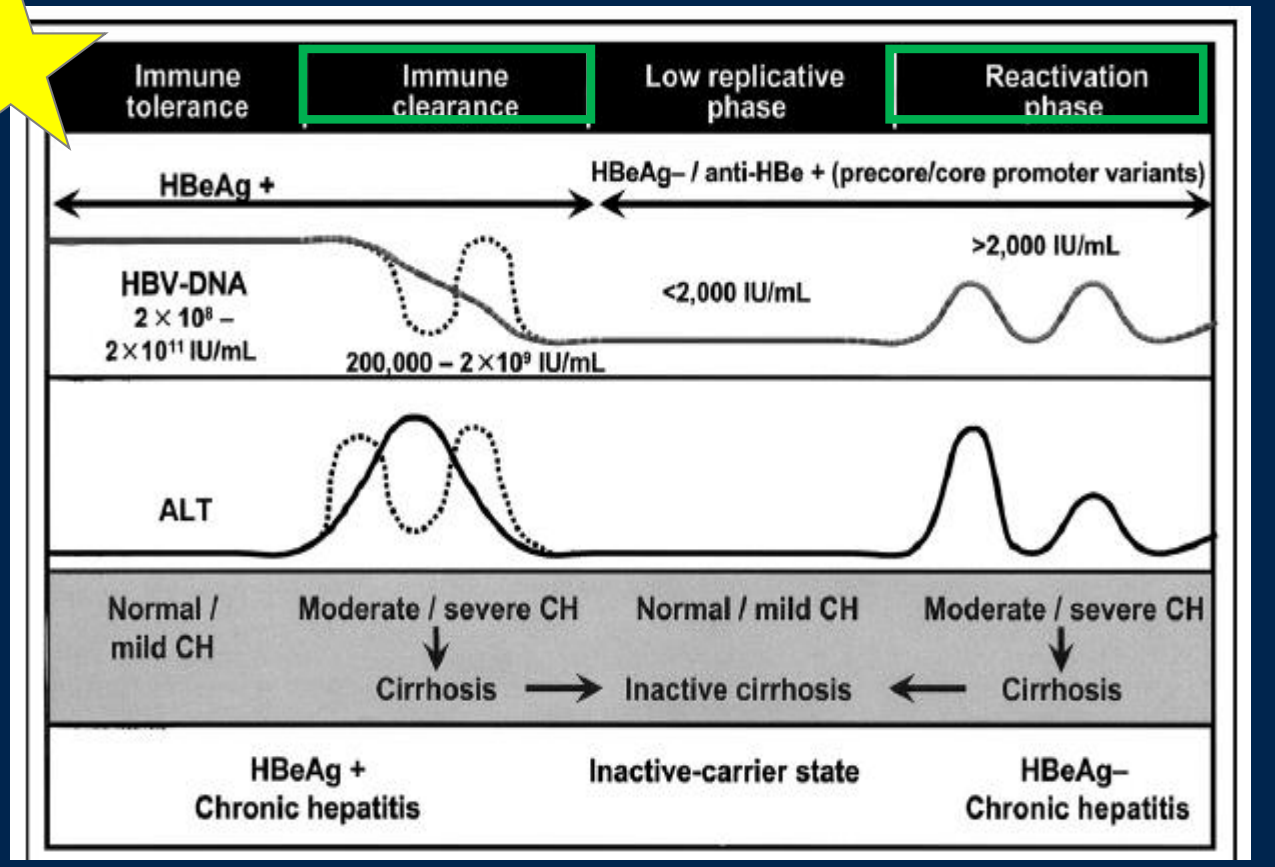
Progression to Chronic Hepatitis B Virus Infection



Texas Children's Hospital®

Baylor College of Medicine

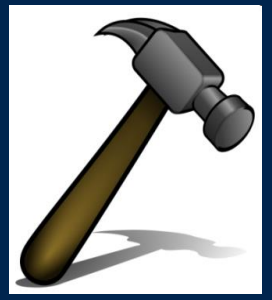
Phases of chronic Hepatitis B



Diagnosis of Chronic Hepatitis B and the Implications of Viral Variants and Mutations
Robert G. Gish, MD *The American Journal of Medicine (2008) 121, S12–S21*

Hep B Seroconversion

- Among HBeAg+ children with elevated serum ALT levels, the rate of spontaneous HBeAg clearance varies from 8-15%/yr

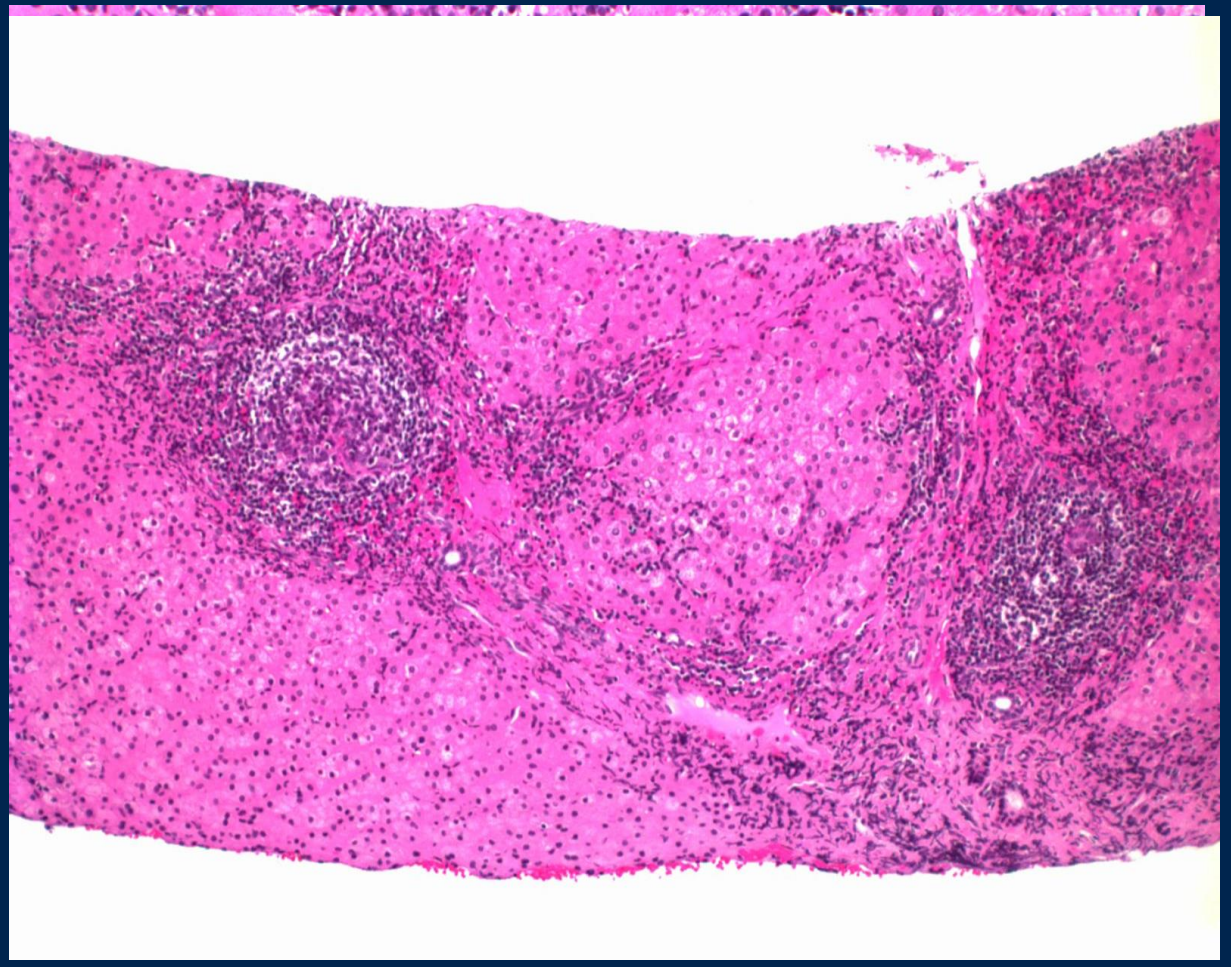


All new HBeAg+ children should be monitored for 6-12 months before considering antiviral therapy.

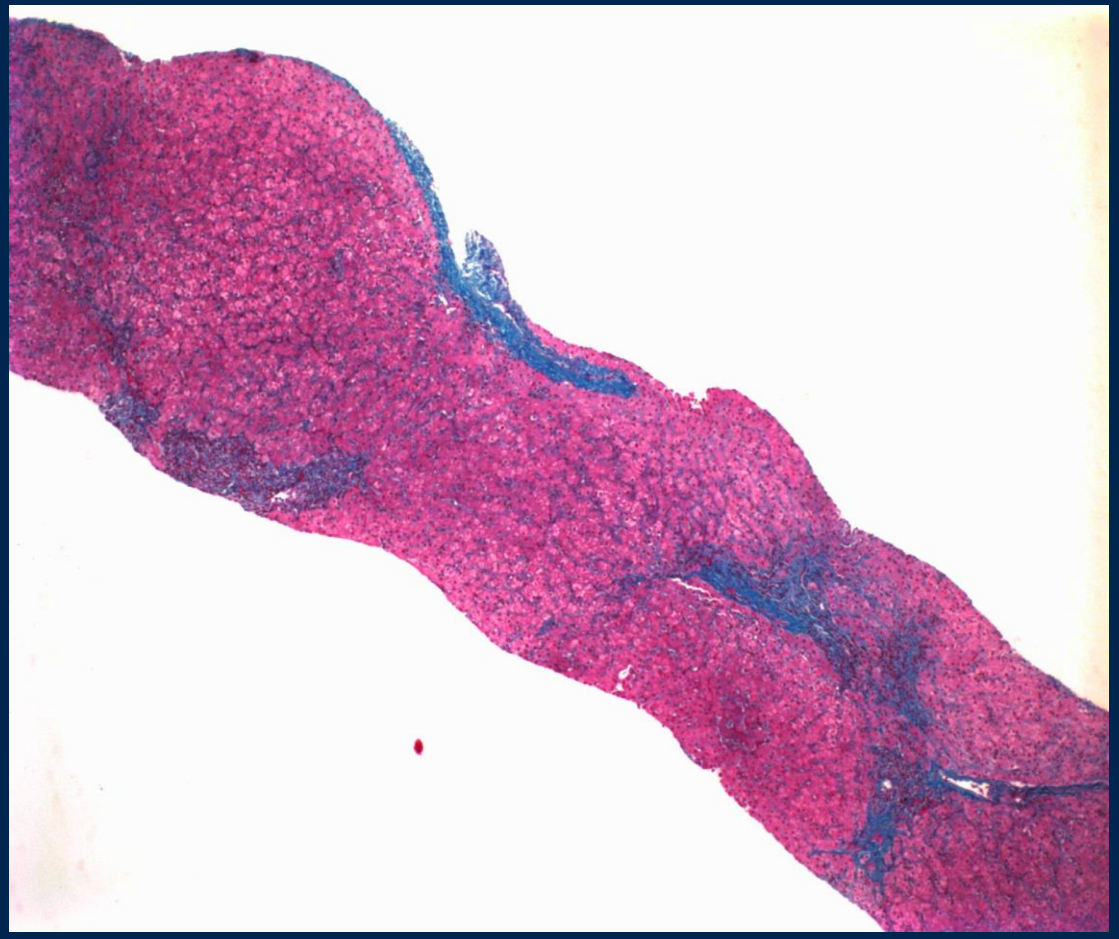
Decision to Treat

- Generally considered in chronic HBV+ children in the immune reactive phase (ALT >2 x ULN and HBV DNA >20,000 IU/mL, for at least six months)
- **Inflammation/fibrosis on biopsy**
- Patient and family decision

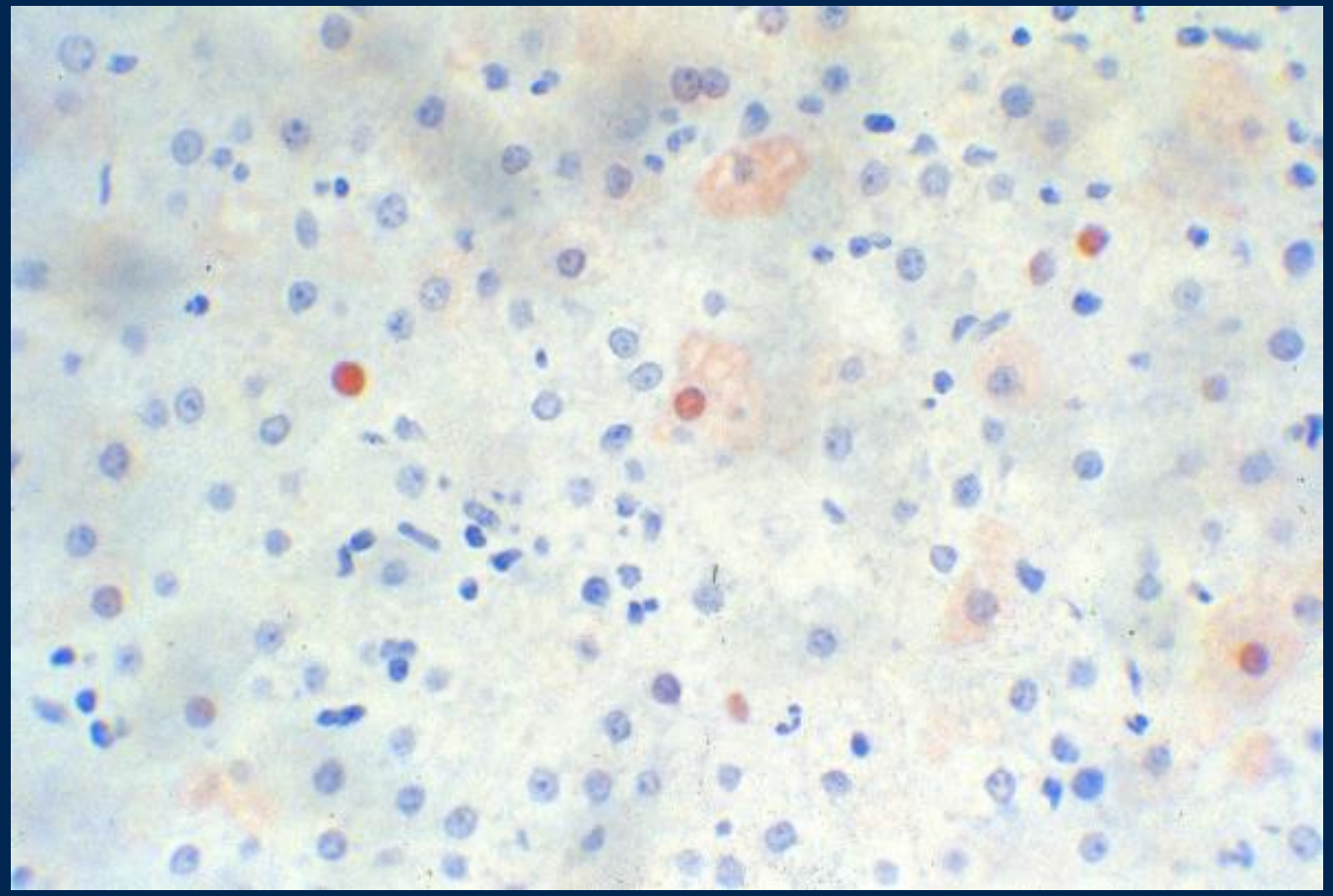
14 year old Russian female with ALT 150 and HBV DNA of 10^5 IU/mL



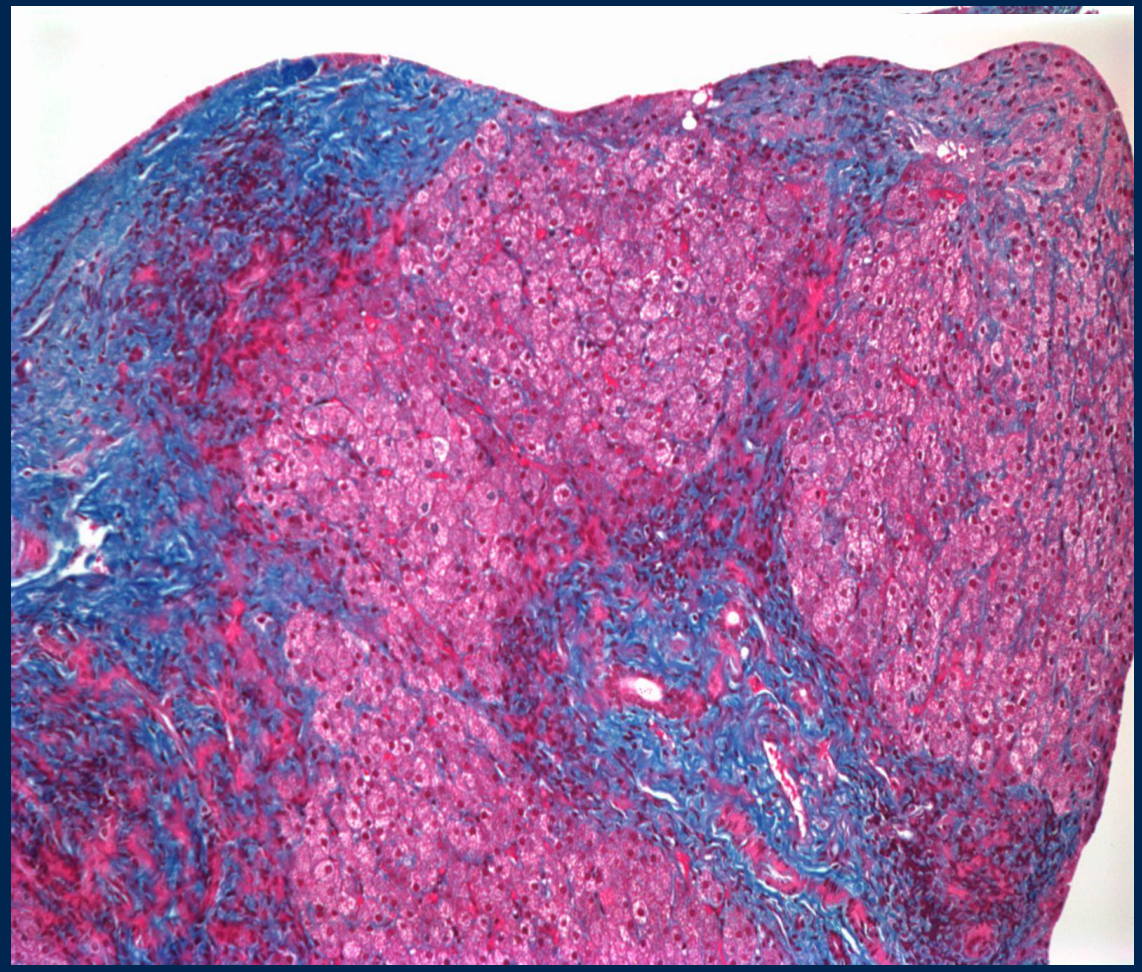
14 year old Russian female with ALT 150 and HBV DNA of 10^5 IU/mL



2 year old adopted EAg+ Chinese female with ALT of 50, HBV DNA of 10^8 IU/mL



2 year old adopted EAg+ Chinese female with ALT of 50, HBV DNA of 10^8 IU/mL



Guidelines for treatment of HBeAg positive infection

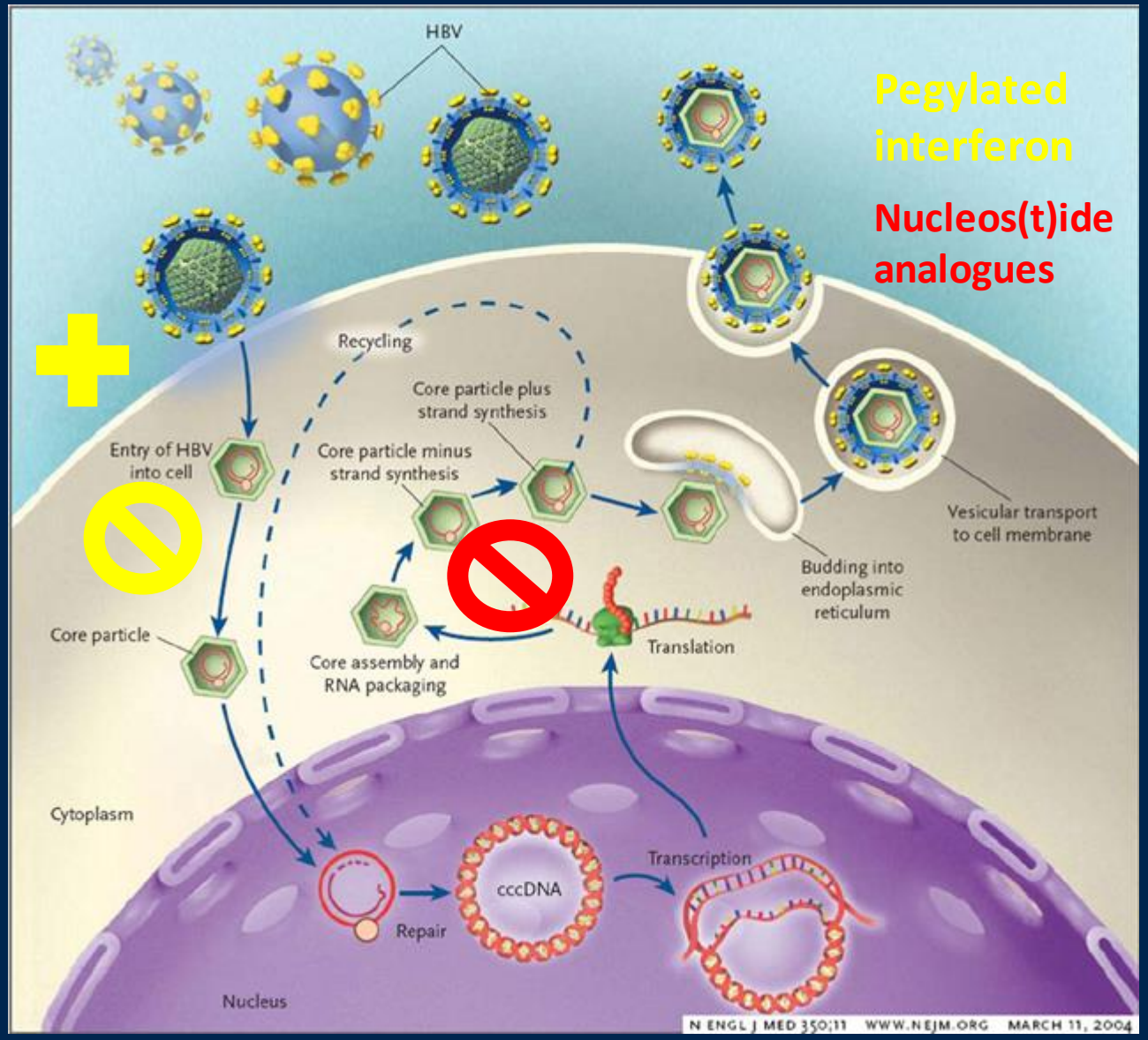
HBV DNA (IU/ml)	ALT	Treatment Strategy
<20,000	normal	No treatment Monitor every 6-12 months
≥20,000	normal	Lower rate of HBeAg seroconversion with therapy Consider biopsy if treatment is being considered
≥20,000	elevated	Treat

Lok and McMahon. Hepatology, Vol. 45, No. 2, 507-539. 2007

Goal of Hepatitis B Treatment

- Suppression of Viral Replication
  - -Less resistance, ↓ risk of cirrhosis/HCC, improved histology
- Seroconversion
  - -eAg + to eAg-/eAb +, clinical remission, ↓ in fibrosis, sAg loss
- Normalization of ALT
- Avoid precore escape mutations

Lau, George. Current treatments for patients with HBeAg-positive chronic hepatitis B virus infection: a comparison focusing on HBeAg seroconversion. Liver International ISSN 1478-3223. Jan 2010
Hui CK, Leung N, Shek TW, et al. Sustained disease remission after spontaneous HBeAg seroconversion is associated with reduction in fibrosis progression inchronic hepatitis B Chinese patients. Hepatology 2007; 46:690–8.



New England Jnl of Medicine , March 2004 Vol 351:1567-1570

Treatment options in children

PEDIATRIC APPROVED

Agent	Pros	Cons	Use
Lamivudine **FDA >3 yrs**	Oral, Excellent tolerance, 1 yr 15% seroconversion, 5 yr 40%	Drug resistance common (20% per year to 70% by year 5)	**No** 
Peg Interferon-α **FDA >3 yr**	HBsAg loss 8%, short treatment duration, no drug resistance, E antigen seroconversion ~30%	**Poor tolerance**:flu-like, psych, myelosuppresion, injection. Genotype C poor response	**Yes?** 
Adefovir No FDA >12 yrs	Oral, Excellent tolerance, Use in ESLD and in Lamivudine failures	Less potent with suboptimal responses. Nephrotoxic. 30% Drug resistance (yr 1=0%, yr 2= 1.2%, yr 4=18%, yr 5=29%)	**No** 
Entecavir **FDA 2014** **>2 yrs**	High potency against DNA. Oral, Excellent tolerance. Only 1.7% resistance over 6 years. Use in Lamivudine/Adefovir failures	Drug resistance common in patients with lamivudine resistance (32% by yr 3)	**Yes** 
Tenofovir **FDA 2018** **>2 years**	More potent than Adefovir, similar to Entecavir. Use in pregnancy, HIV, minimal SE. 0% resistance	Some nephrotoxicity in select cases. Very new. Cross Resistance with Adefovir	**Yes?** 

Phenotype responsive to IFN

- ALT>2 ULN
- HBV DNA <200 million IU/mL (2X10^8)
- Genotypes A or B
  - -37% of A show sustained response
  - -25% of B show sustained response
  - -20% of C show sustained response
  - -8% of D show sustained response

Tenofovir vs Entecavir vs pegIFN

Table 1. Efficacy of Antivirals for the Treatment of Chronic Hepatitis B Virus[a, 2, 14–16]

Drug, Dosage, and Duration	HBeAg+ Chronic HBV: HBeAg Seroconversion (%)	HBeAg+ Chronic HBV: HBV DNA Negative (%)	HBeAg– Chronic HBV, HBV DNA Negative (%)	Development of Resistance (%)
Interferon alfa-2b 5 MU q.d. or 10 MU 3 times/wk x 12–48 wks	18	37	60–70	NA
Pegylated interferon alfa-2a 180 µg q wk x 48 wks	27	25	63	NA
Lamivudine 100 mg q.d. x 48–52 wks	16–21	40–44	60–73	23
Adefovir 10 mg q.d. x 48 wks	12	21	51	0 (naïve), 0–18 (lamivudine resistant)
Entecavir 0.5 mg q.d. x 48 wks	21	67	90	0.1 (naïve), 6 (lamivudine resistant)
Telbivudine 600 mg q.d. x 52 wks	22	60	88	4.4 (HBeAg+), 2.7 (HBeAg–)
Tenofovir 300 mg q.d. x 48 wks	21	76	93	0

Data are percentages of patients.
HBeAg = hepatitis B e antigen; HBV = hepatitis B virus; MU = million units; NA = not applicable.
[a]Efficacy was assessed up to 52 wks.

Jenh AM et al. Tenofovir for the treatment of hepatitis B virus. Pharmacotherapy. 2009 Oct;29(10):1212-27.

Treatment failure

- Primary treatment failure with IFN= < 1 log reduction in serum HBV DNA from baseline level at week 12.

- Primary treatment failure with NA's=< 2 log decrease in HBV DNA by 6 months
  - -Switch to another agent or another agent added

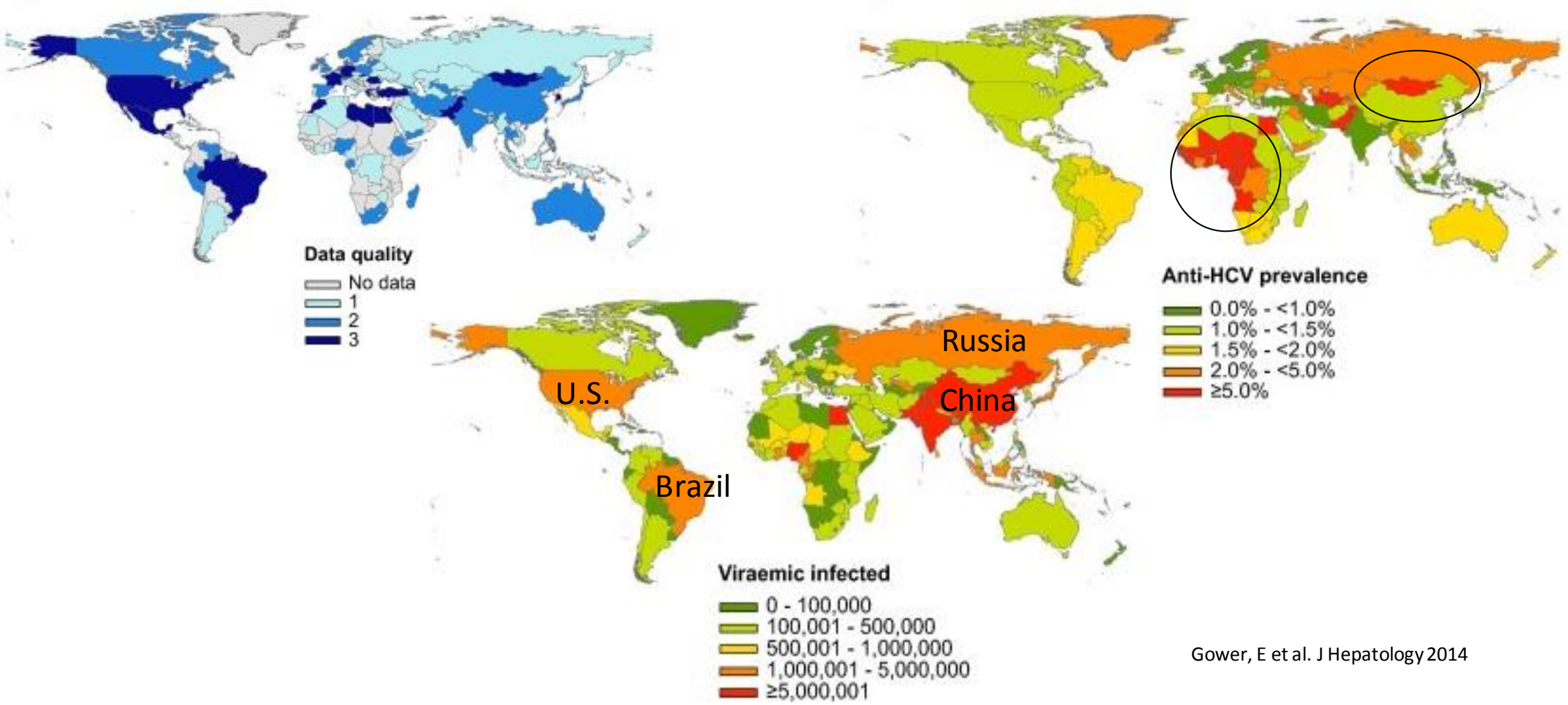
Treatment Success

- eAg loss with eAb formation (seroconversion)
- Undetectable to low HBV viremia (<2000)
- sAg loss
- Consolidate treatment up to 12-18 months post seroconversion
  - Consider quantitative sAg level to inform timing to stop NA

Summary: Pediatric HBV

- Fibrosis can occur at an early age
- IFN “may” be a good first option if child is a candidate but has systemic SE’s. Higher rates of eAg seroconversion
- Entecavir and Tenofovir are much more potent antivirals and are safe and effective

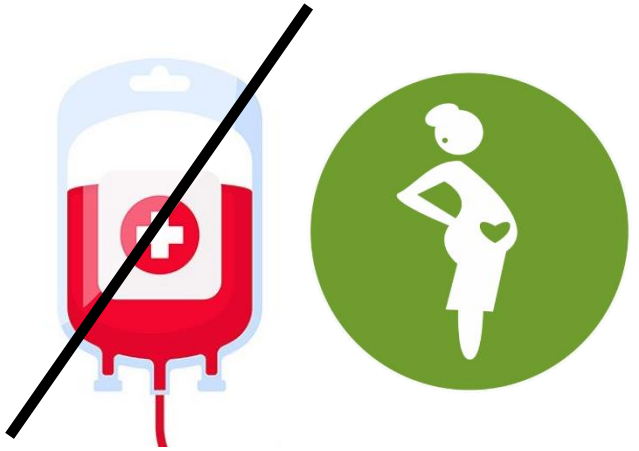
5 million children and adolescents with HCV infection worldwide

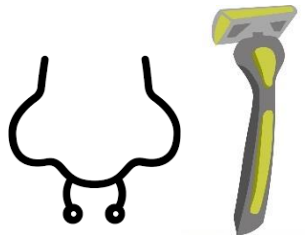


Gower, E et al. J Hepatology 2014

Transmission and epidemiology in U.S.

- **2.5 million people with hepatitis C in the U.S**
- **Vertical** transmission (3-10%) is the most common route in infants and children with approximately **7,500 new cases/year** in the US.
- Horizontal transmission occurs primarily via **injection drug use** (60% of all HCV infections)
- Tattoos, piercings, razors, intranasal cocaine: inconclusive but potential modes of HCV acquisition



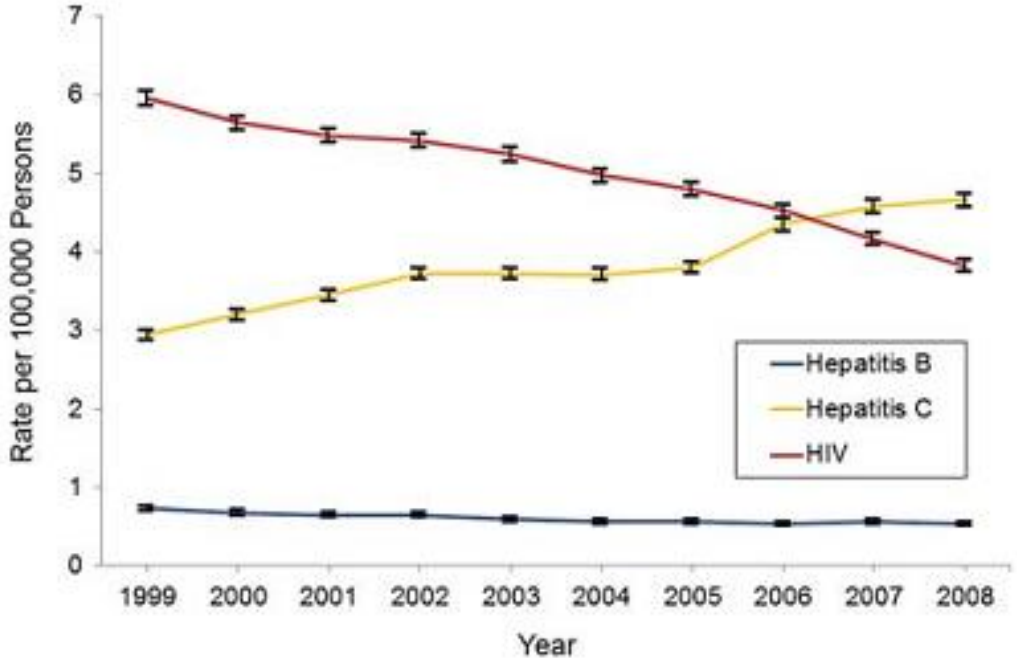


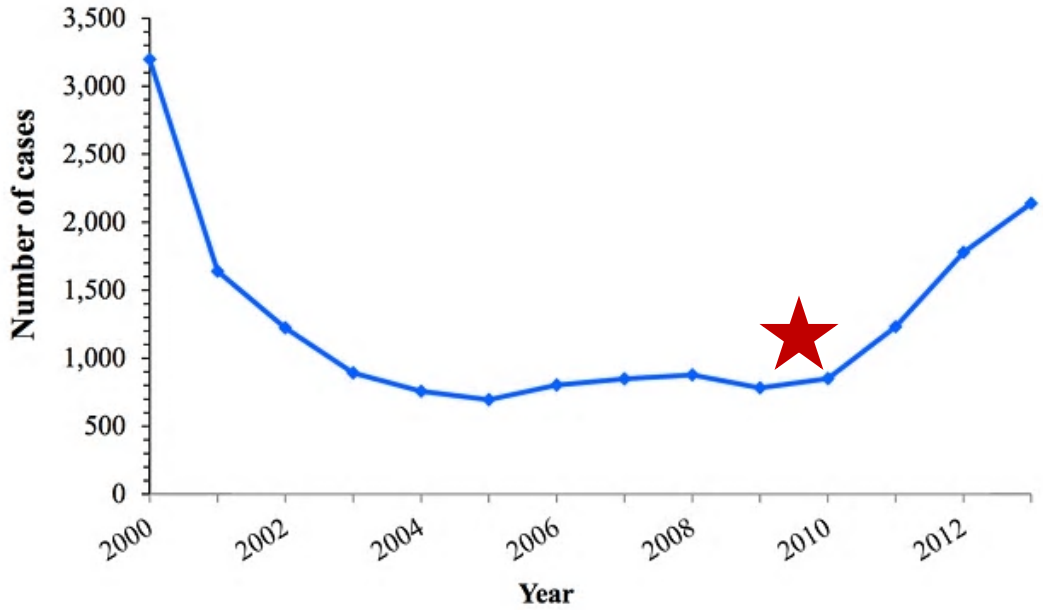
Jhaveri R. et al. J Pediatr 2006
Alter MJ et al. Ann Intern Med 2006

El Saadany S. et al. Can J Gastroenterol 2000
Edline, BR et al. Heaptology 2015

HCV on the Rise. Why?

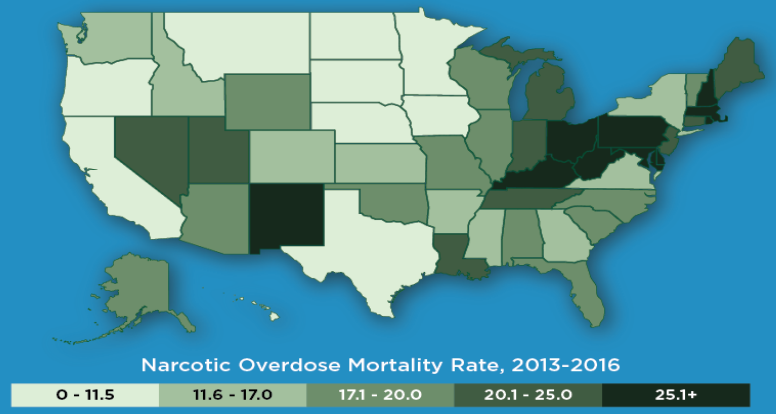
- Prevalence rates are rising, ranging from 0.05%-0.36% in the United States and Europe
- Acute hepatitis C infections increased **250% from 2010 to 2014.**



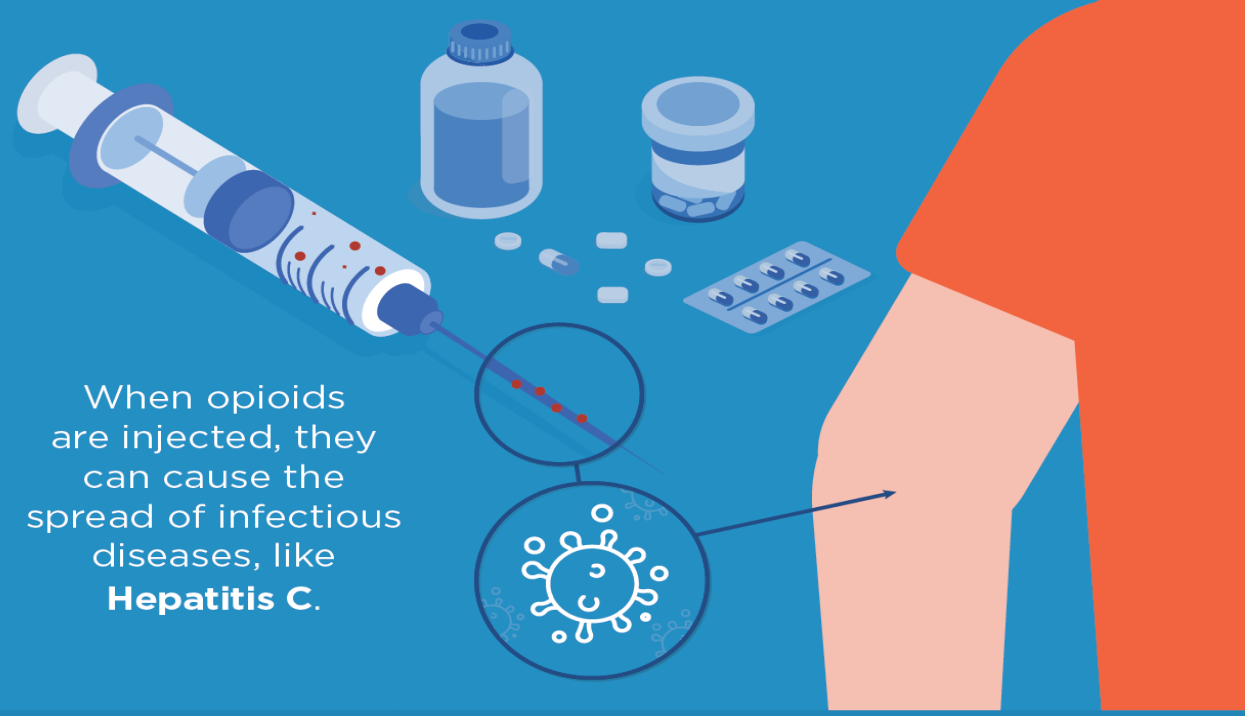


Holberg SD et al. Evolving epidemiology of hepatitis C virus in the United States. Clin Infect Dis. 2012 Jul;55 Suppl 1:S3-9.
Averhoff FM, et al. Global burden of hepatitis C: considerations for healthcare providers in the United States. Clin Infect Dis 2012

THE OPIOID EPIDEMIC AND HEPATITIS C IN THE UNITED STATES



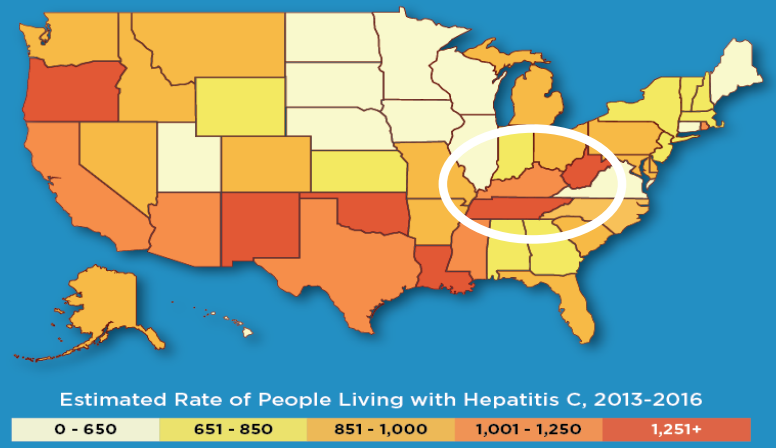
In 2017, injection drug use contributed to the nearly **48,000 opioid-related overdose deaths**.



When opioids are injected, they can cause the spread of infectious diseases, like **Hepatitis C**.

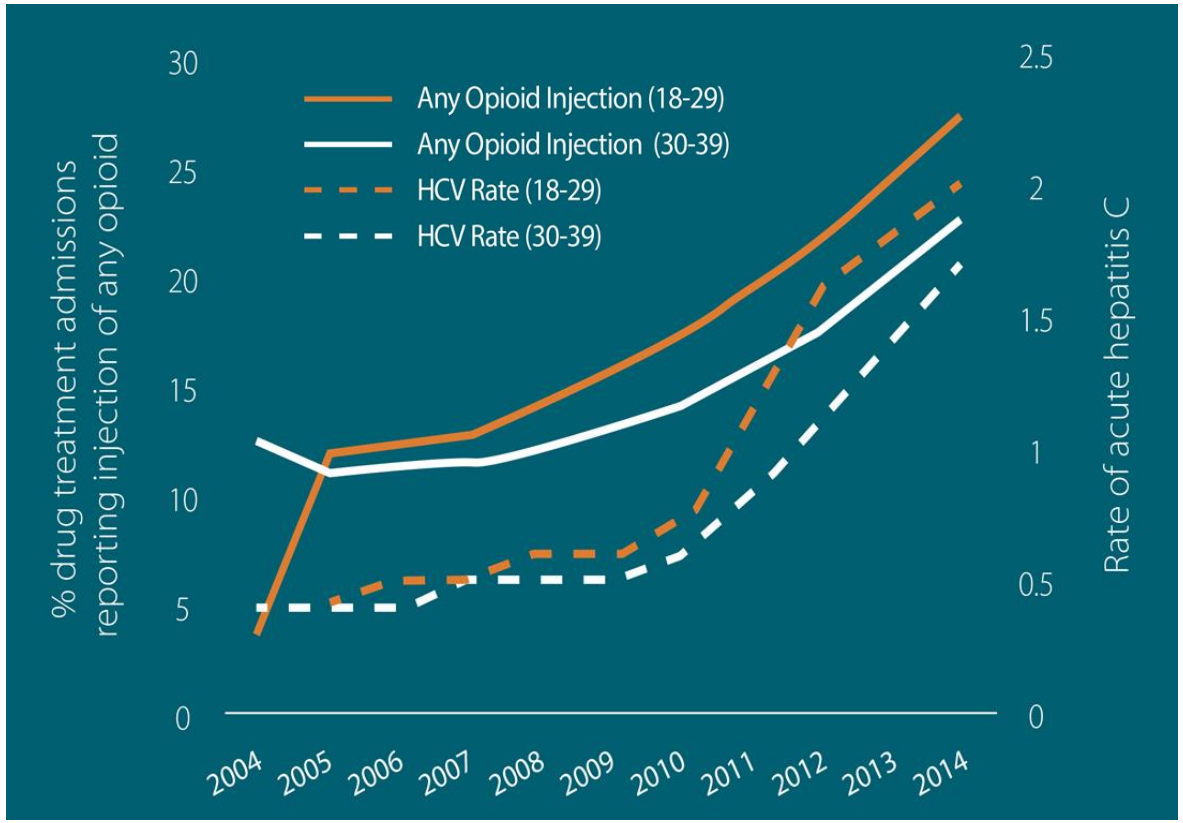
350% INCREASE IN NEW HEPATITIS C INFECTIONS 2010-2016

Since 2005, **new Hepatitis C infections** have been rising particularly among **young people**, likely due to **injection drug use**.



Geographic areas experiencing the **highest burden of opioid use disorder** are also experiencing higher rates of Hepatitis C.

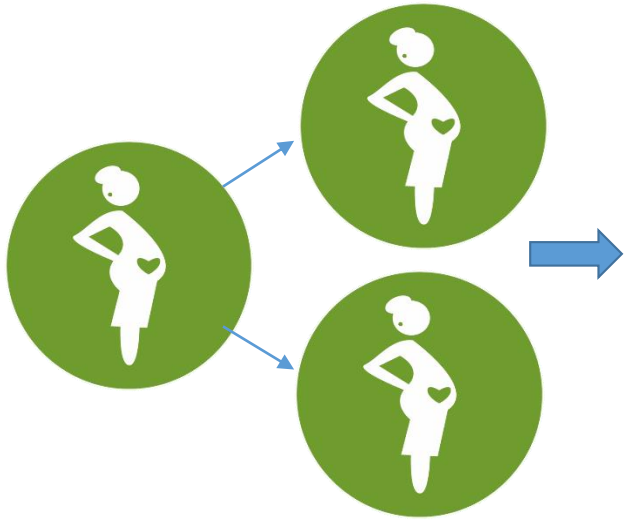
HCV and Opioid Injection rose in parallel



- Among people, aged 18-29, HCV increased by 400% and admissions for opioid injections by 622%
- Among people aged 30-39, HCV increased by 325% and admissions for opioid injections by 83%

CDC and Prevention and Substance Abuse and Mental Health Services Administration

The Face of HCV is getting younger



Baby boomers: Born between 1945-1965

- Increase in the use of injections, blood products and illicit drugs following WWII

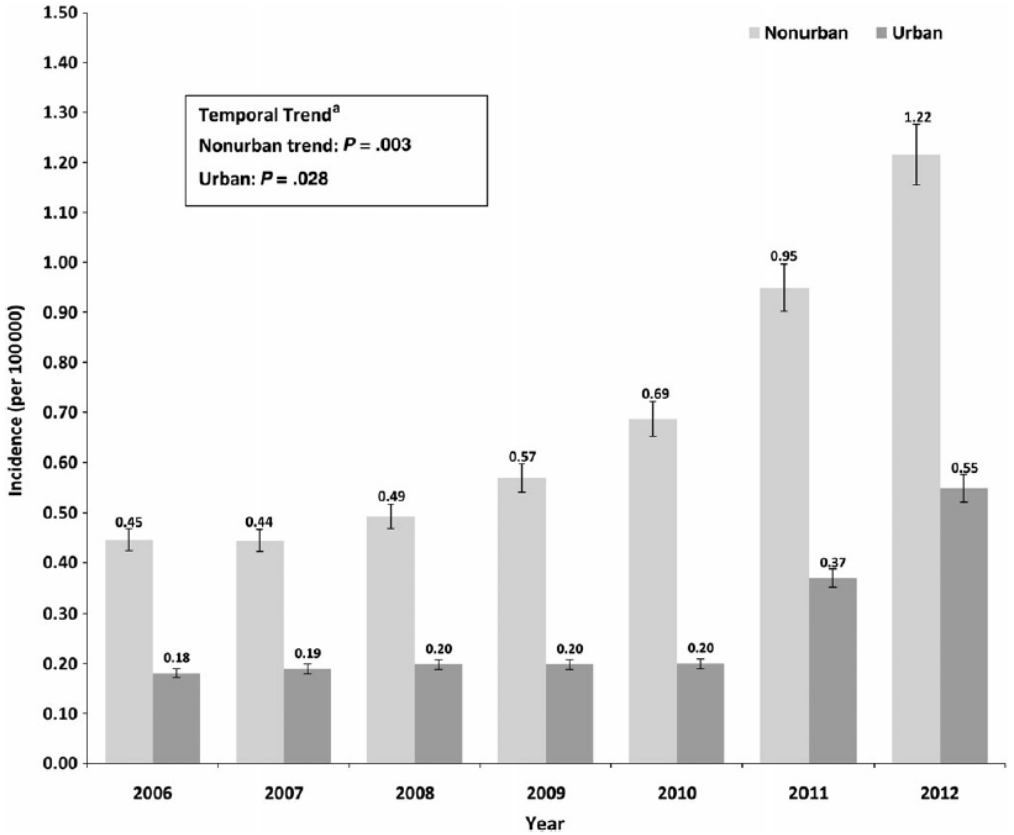
Gen X, Millenials, and Gen Z: Born between 1975-2002

Maternal HCV infections doubled among reporting U.S. states

- Rural
- White

Patrick SW, et al. MMWR Morb Mortal Wkly Rep 2017;66:470–473.
Chappell CA, et al. Hepatitis C Virus Screening Among Children Exposed During Pregnancy. Pediatrics 2018

What can We Do?



- Recognize higher risk of HCV within **rural populatons**
- **PCR testing children of HCV+ mothers at 2 months** of age may be considered
- Be aware of and support drug **treatment and recovery services**
  - Medication-assisted treatment
  - Clean needle exchange
  - Education
  - Medical point of care access

Suryaprasad AG et al. Clin Infect Dis 2014

Panel A-IHG. Hepatitis C Guidance 2018 Update: AASLD-IDSA recommendations for testing, managing, and treating hepatitis C virus infection. Clin Infect Dis 2018

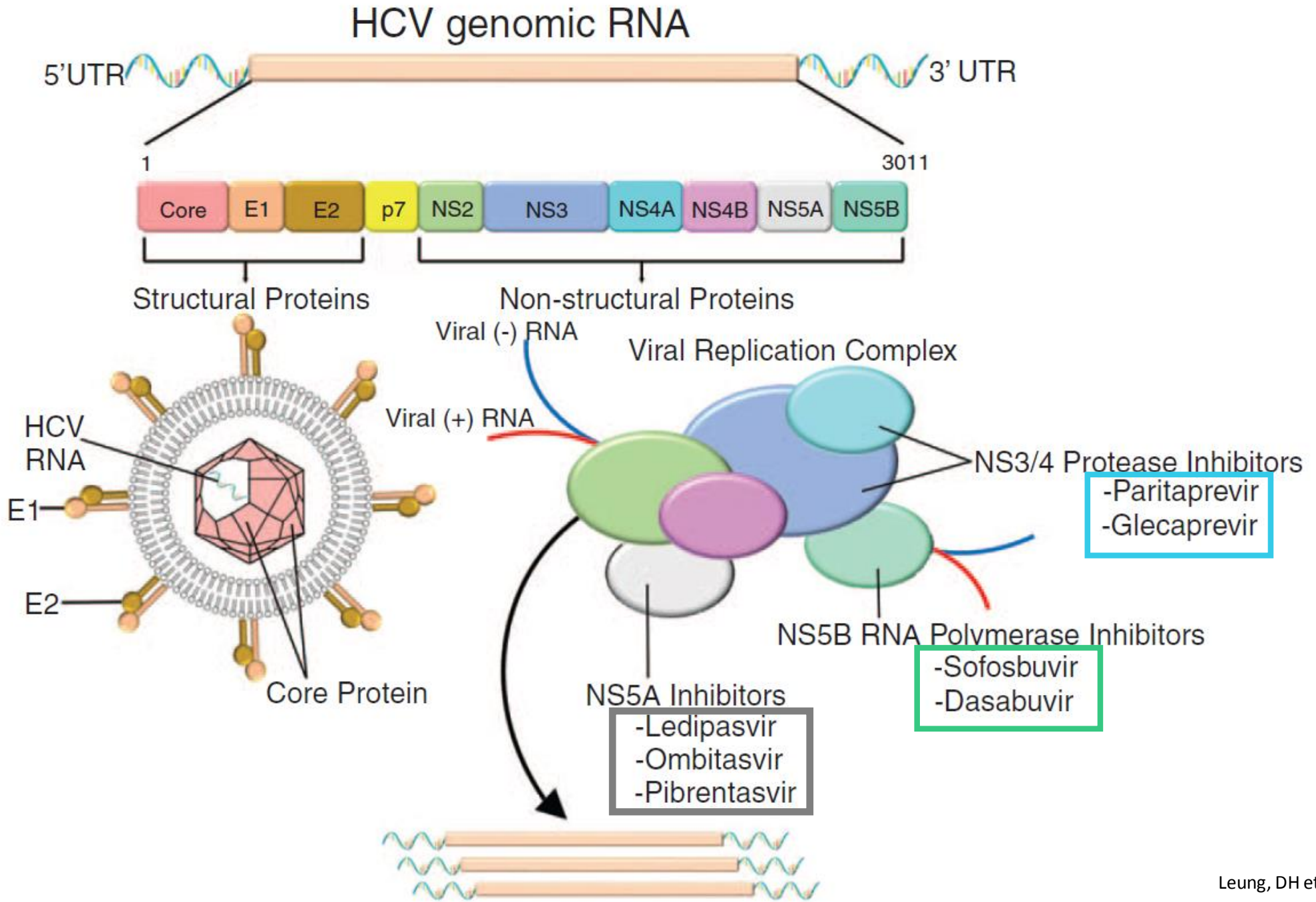
Who Should Be Treated?

THEN

- Elevation of liver transaminases
- Fibrosis on liver biopsy
- Personal or family history of early cirrhosis or HCC

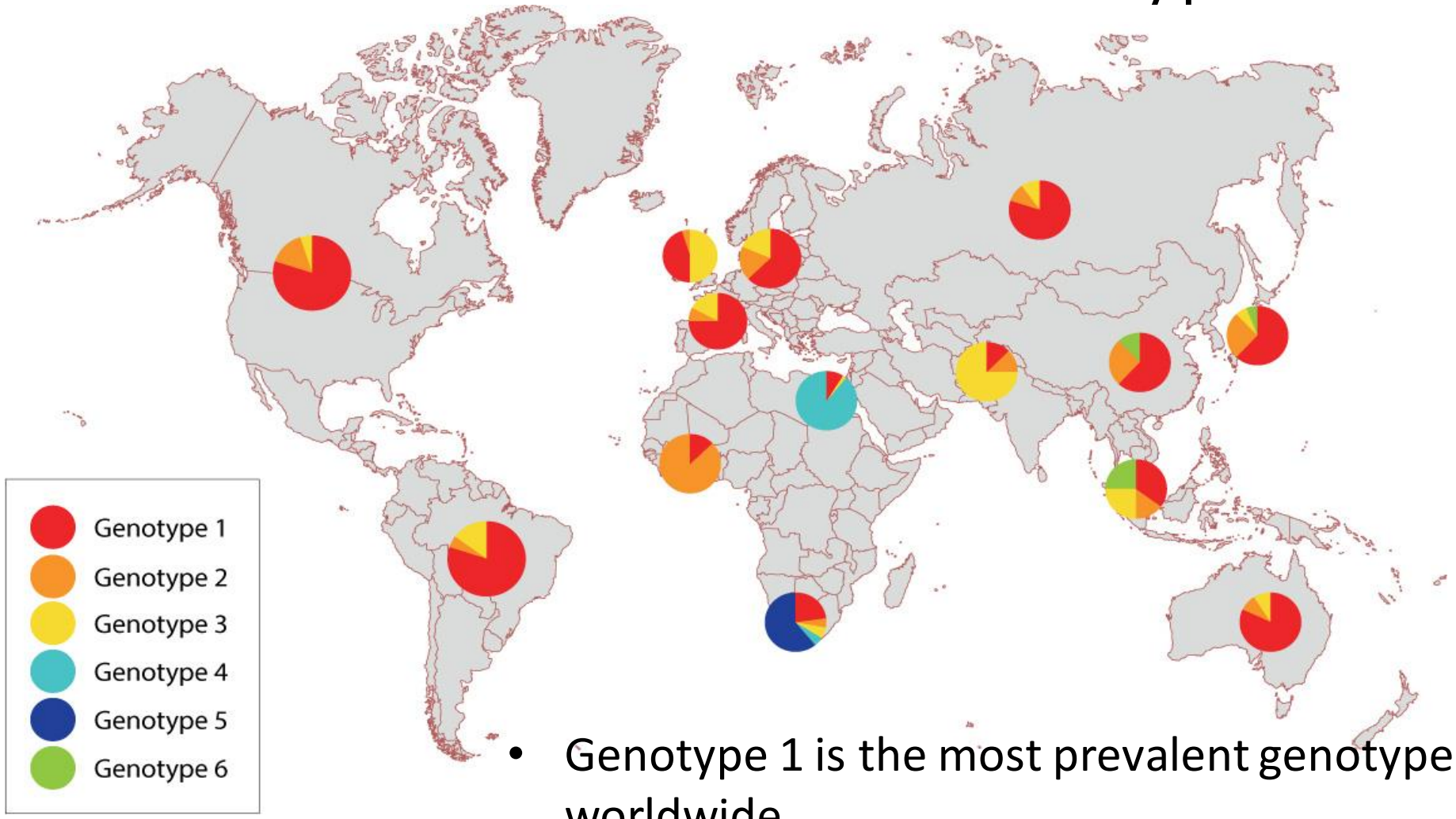
NOW

- At least 3 years of age
- HCV viremia



Leung, DH et al. JPGN 2020

Global Distribution of HCV Genotypes



WHO.gov

- Genotype 1 is the most prevalent genotype worldwide
  1b in Europe and **1a in US**

TABLE 2. Direct-acting antivirals studied in children with chronic hepatitis C

Study, year	DAAs	Age (y/o)	HCV GT	Sample size	SVR12	Most Common AE	SAE
Balistreri et al, 2016 (136)	Ledipasvir/sofosbuvir (90 mg/400 mg)	12–17	1 (a and b)	100	98%	Headache (27%), diarrhea (14%), fatigue (13%)	None
Wirth et al, 2017 (137)	Sofosbuvir (400 mg) and ribavirin (weight-based)	12–17	2 and 3	52	98%	Nausea (27%), headache (23%)	None
Murray et al, 2018 (138)	Ledipasvir/sofosbuvir (45 mg/200 mg) and ribavirin (weight-based)	6–11	1, 3, and 4	92	99%	Headache (18%), pyrexia (17%)	One case (tooth abscess), not related to study treatment
Leung et al, 2018 (139)	Ombitasvir/paritaprevir/ritonavir ± dasabuvir ± ribavirin	12–17	1 and 4	38	100%	Headache (21%), fatigue (18%), nasopharyngitis (13%)	None
Rosenthal et al, 2019 (140)	Sofosbuvir and ribavirin (weight based)	3–11	2 and 3	54	98%	6–11 y: Vomiting (32%), headache (29%); 3–5 yr: Vomiting (46%), diarrhea (39%)	RBV overdose
Schwarz et al, 2019 (141)	Ledipasvir/sofosbuvir (weight-based)	3–5	1 and 4	34	97%	Vomiting (24%), cough (21%), pyrexia (21%)	None
Jonas et al, 2019 (142)	Glecaprevir/pibrentasvir (300 mg/120 mg)	12–17	1, 2, 3, or 4	47	100%	Nasopharyngitis (26%) URI (19%)	None

NS5B NS5A NS3/4

Leung, DH et al. JPGN 2020

4 FDA-approved DAA's for children with HCV

- For genotypes **1, 4, 5, or 6** in children **≥ 12 years** or **≥ 35 kg** in weight
  - **April 2017**, the FDA first approved the combination of ledipasvir (LDV) sofosbuvir (SOF) **once daily** for **12 weeks * †**
    - ≥35 kg: Pellets, tablets: Oral 90 mg ledipasvir 400 mg sofosbuvir once daily.
  - **September 2019**, this approval was further extended down to age **3 years** of age
    - <17 kg: Pellets: Oral: 33.75 mg ledipasvir 150 mg sofosbuvir once daily.
    - 17 to <35 kg: Pellets, tablets: Oral 45 mg ledipasvir 200 mg sofosbuvir once daily.

NS5A + NS5B

- For genotypes **2 and 3** in children **≥ 12 years** or **≥ 35 kg** in weight
  - **April 2017**, SOF with ribavirin (RBV, 15 mg/kg in 2 divided doses) for **12 weeks** was approved by the FDA in children
  - **August 2019**, this approval was further extended down to age **3 to 11 years**

NS5B

NS5B NS5A NS3/4

4 FDA-approved DAA's for children with HCV

- **All** genotypes in children **≥ 3 years (June 2021) and ≥12 years (April 2019)**
  - Combination of glecaprevir (GLE) and pibrentasvir (PIB) for **8 weeks** (naïve, no cirrhosis) **or 12 weeks** (treatment experienced, +/- cirrhosis)

Body Weight (kg) or Age (yrs)	Daily Dose of glecaprevir/pibrentasvir	Dosing of MAVYRET
Less than 20 kg	150 mg/60 mg per day	Three 50 mg/20 mg packets of oral pellets once daily
20 kg to less than 30 kg	200 mg/80 mg per day	Four 50 mg/20 mg packets of oral pellets once daily
30 kg to less than 45 kg	250 mg/100 mg per day	Five 50 mg/20 mg packets of oral pellets once daily
45 kg and greater OR 12 years of age and older	300 mg/120 mg per day	Three 100 mg/40 mg **tablets** once daily[1] (see Recommended Dosage in Adults)

NS3/4 + NS5A

MAVYRET
glecaprevir/pibrentasvir
100 mg/40 mg tablets

NS5B NS5A NS3/4

4 FDA-approved DAA's for children with HCV

- **All** genotypes in children **≥ 6 years or ≥ 17 kg** in weight
  - **March 2020**, FDA approved the combination of sofosbuvir (SOF) velpatasvir (VEL) for **12 weeks**
    - **17 to <30 kg: Tablet: 200 mg sofosbuvir/50 mg velpatasvir once daily.**
    - **≥30 kg: Tablet: 400 mg sofosbuvir/100 mg velpatasvir once daily.**
    - **In June 2021,** pediatric indication approved down to 3 years and older

NS5B + NS5A

Body Weight (kg)	EPCLUSA Daily Dose	Dosing of EPCLUSA Oral Pellets	Dosing of EPCLUSA Tablet
less than 17	150 mg/37.5 mg per day	one 150 mg/37.5 mg packet of pellets once daily	N/A
17 to less than 30	200 mg/50 mg per day	one 200 mg/50 mg packet of pellets once daily	one 200 mg/50 mg tablet once daily
at least 30	400 mg/100 mg per day	two 200 mg/50 mg packets of pellets once daily	one 400 mg/100 mg tablet once daily[a]

NS5B NS5A NS3/4

Safe, Simple, Swift, and Successful

- **Safe** and **highly effective**

- The promise of a **once-daily, patient tailored** (ie, HIV co-infection, renal insufficiency, with or without cirrhosis), **single pill treatment** with a **>95% cure** and **minimal side effects** for children is now available.

Barriers to cure with approved DAA's in children with HCV

- Cost $$
- Medical restrictions
- Paperwork/Appeals
- Adherence/Palatability

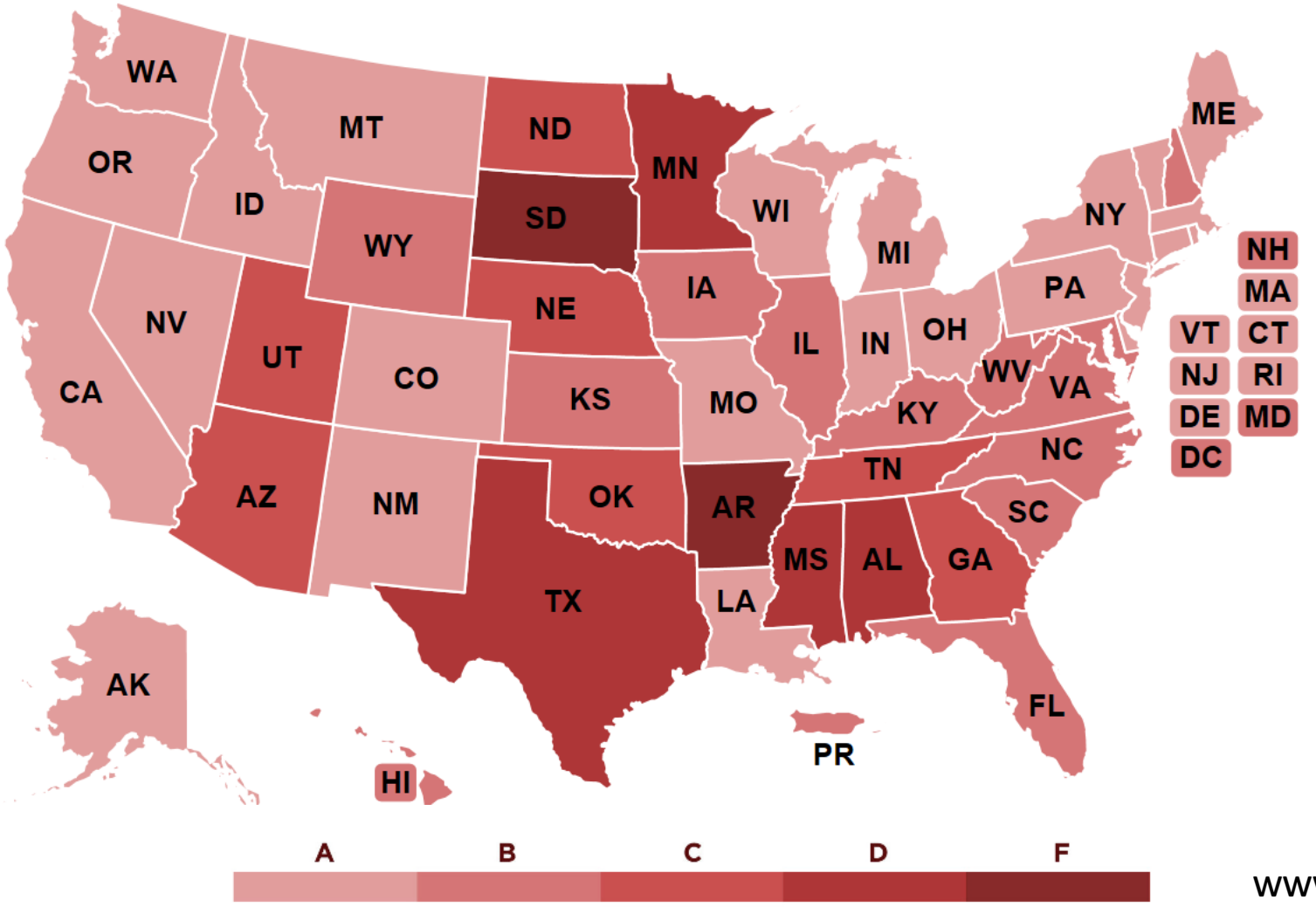
The Price of Treatment

- If paying by cash, Harvoni™, Epclusa™ Mavyret™, Zepatier™ can cost between $26,000-75,000 for a 12-week treatment[1]
- In some cases, nearly $1000 per pill

Actual cost paid for the medications may be significantly lower. Patient assistance and support programs available as low as $5 per co-pay with commercial insurance

1. Henry, B. Drug Pricing and Challenges to Hepatitis C Treatment Access. J Health Biomed Law. 2018 Sep; 14: 265–283.
2. Drugs.com/price-guide

More than 50% of Medicaid programs received a "D" or "F" for severely restricting access to DAA's



www.stateofhepc.org

Insurance Plans Restrictions or Peer to Peer

- Controlling drug costs by placing restrictions on access to DAAs that focus on

a) **Fibrosis severity**

- Liver biopsy
- Fibroscan
- Fibrotest

B.) **Sobriety** (**any positive drug test is a failure**)

C.) **Type of prescriber**

Texas Medicaid Forms for DAA's

Health and Human Services

Texas Vendor Drug Program

Antiviral Agents for Hepatitis C Virus Initial Authorization Request (Medicaid)

March 2018-E

Part I. Prior Authorization Criteria and Policy

I. Eligibility

1. Patient is enrolled in Texas Medicaid.
2. Patient is greater than or equal to 12 years of age if Harvoni eligible. Patient is greater than or equal to 18 years of age for all other products.
3. Patient has a diagnosis of chronic hepatitis C virus (HCV) with a confirmed genotype of 1a, 1b, 2, 3, 4, 5 or 6. Genotype test results must be obtained within the previous 5 years from the date of prior authorization request.
4. Immediate treatment is assigned the highest priority for patients with advanced fibrosis (Metavir stage F3) or cirrhosis (Metavir stage F4), liver transplant recipients, and patients with hepatocellular carcinoma. Patients with Metavir scores less than stage 3 may not be approved.
5. Prescriber should be a Board Certified Gastroenterologist, Hepatologist or Infectious Disease physician. A prescriber other than the above specialists may prescribe and assume responsibility and care for the patient when the prescriber is supervised by a specialist, or with consult from a specialist from the previous 90 days. A copy of written consult must be submitted. *Exceptions may be considered when a specialist is not available.*
6. Required laboratory values in Section 3 of the form must be obtained within 90 days prior to the request for HCV treatment.
7. Q80K polymorphism testing is required for requests for treatment with Olysio within the previous two years.
8. NS5A resistance testing is required for requests for treatment with Daklinza or Zepatier in genotype 1a patients within the previous two years.
9. Child-Turcotte-Pugh Score must be assessed within 90 days prior to the request for HCV treatment.
10. Female patients' pregnancy status must be determined by a pregnancy test prior to the request for HCV treatment. The pregnancy test should be conducted as close to the start of treatment as possible, but no later than 90 days prior to the request. Pregnancy status must be confirmed negative for all ribavirin containing regimens. Pregnancy status is not required for age greater than 50, or for those documented as not able to become pregnant.
11. Patient must have one drug screening within 90 days prior to the request for HCV treatment.
12. Patient must be assessed for hepatitis B coinfection within 90 days prior to the request for HCV treatment.
13. Prescriber must provide required lab results at baseline, and at treatment week four and at week 12.
14. Documentation of any additional supporting labs must be provided if requested by the patient's health care plan.

- Stage 3 fibrosis?
- Required labs at W0, W4, and Week 12.
- Prior auth is granted for 6 weeks per approval. HHS Form 1336 should be submitted by week 6, and every 6 weeks thereafter

Part III. Initial Prior Authorization Request

Please complete and **fax all required documents to Navitus at (855) 668-8553** for initial prior authorization requests. **Prior authorization will be granted for six weeks duration.** Labs are required for weeks 0, 4 and at week 12 for treatments lasting longer than 12 weeks. For refill authorizations please use the *Antiviral Agents for Hepatitis C Virus Initial Authorization Request (Medicaid) (HHS Form 1336).*

1. Client Information

Name (Last, First):	Medicaid ID No.:	Diagnosis (ICD-10):	
Date of Initial Diagnosis:	Date of Birth:	Gender:	Current Weight:

2. Prescriber Information

Name:
Area Code and Telephone No
Consulting/Supervising Physic if applicable:

3. Laboratory *(Results belo*

Laboratory Test	
Baseline HCV RNA level	
ALT	
AST	
AlkPhos	
CrCl	
Scr	
Total bilirubin	

4. Current Patient Status (Check all that apply):

- ☐ Hepatocellular carcinoma
- ☐ Awaiting liver transplant
- ☐ Decompensated cirrhosis
- ☐ Partial responder
- ☐ HIV co-infection
- ☐ Previous liver transplant(s)
- ☐ End stage renal disease requiring hemodialysis
- ☐ Relapsed
- ☐ Hepatitis B co-infection
- ☐ Compensated cirrhosis
- ☐ Null responder

a. If patient has been previously treated for HCV, is the previous treatment regimen(s) known? ◯ Yes ◯ No ◯ N/A

i. If yes, list medications used and any known dates of treatment below.

Prescriber acknowledgment

By signing below, I agree that I have explained the contents of this document, provided written and verbal education to the patient, and answered any questions the patient may have regarding their Hepatitis C treatment.

Prescriber Printed Name | Prescriber Signature | Date

Patient acknowledgment

By signing below, I agree that the doctor has explained the contents of this letter and answered any questions I have regarding my Hepatitis C treatment.

Patient Printed Name | Patient Signature | Date

5. Additional Required Information

a. HCV Genotype:

☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 Date of testing:

(Results must be from previous 5 years)

b. Metavir Fibrosis Stage*:

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 Date of testing:

d methods above for Metavir
se basis.

s 2 years)

s 2 years)

◯ Positive ◯ Negative ◯ N/A Date of testing:

g. Drug Test:

◯ Positive ◯ Negative ◯ N/A Date of testing:

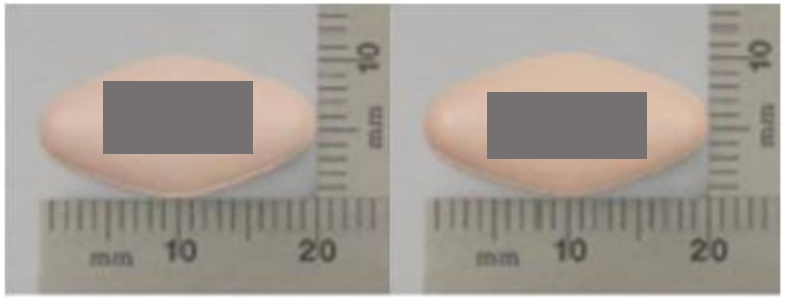
h. Has the patient been assessed for hepatitis B virus coinfection?

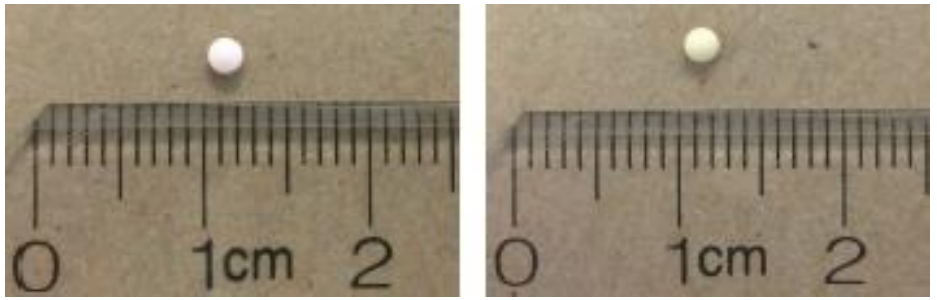
◯ Yes ◯ No Date of testing:

If yes, does the patient require concurrent hepatitis B virus treatment? ◯ Yes ◯ No

Palatability

- #2 most common cause of lack of SVR



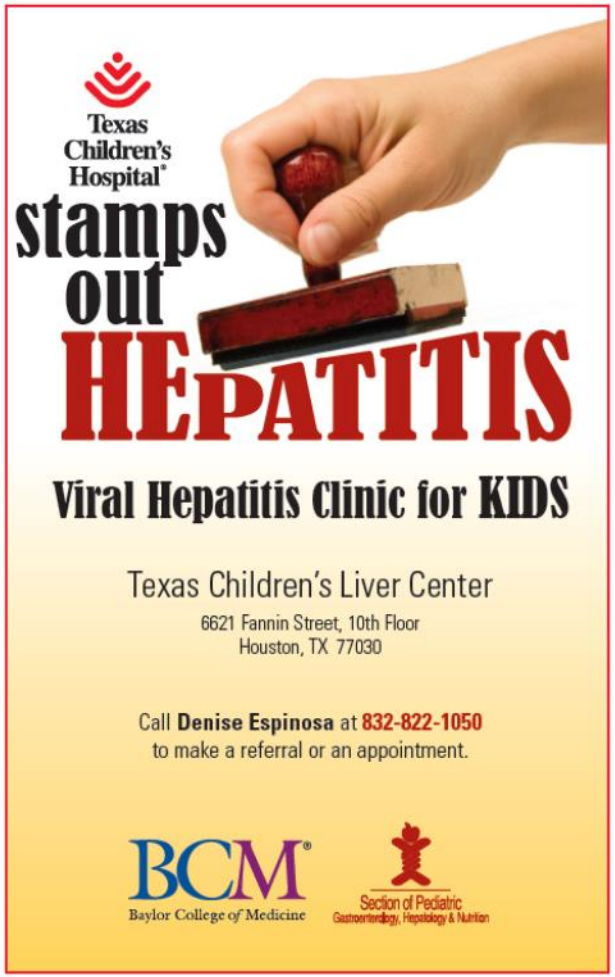


Conclusions

- Face of HCV is changing and becoming younger. Maternal to child transmission will likely increase due to opiate crisis among young adults and women of child bearing age.
- Treatment should be considered and offered to all children with chronic HCV as early as 3 years of age
- DAA's are highly effective and safe, but may not be palatable for younger children.
- We must strongly advocate for and learn how to access FDA-approved DAA combination therapies for all children infected with HCV

Thank you

- dhleung@texaschildrens.org



Texas Children's Hospital

Baylor College of Medicine