Perinatal Hepatitis B and C

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HEPATITIS B

Hepatitis B
Extent of the Problem

- More than 2000 million infected at some time, worldwide
  - 75% in Asia, Western Pacific & sub-Saharan Africa
  - **250**-360 Million with chronic infection (viremia)
  - 686,000 deaths per year (2013)
- Prevalence:
  - > 8% sub-Saharan Africa, Asia, Amazon Basin;
  - 2-8% Middle East, Eastern Europe, Indian subcontinent;
  - < 2% Western Europe, Australia, Americas

Hepatitis B
HBV and Mother to Child Transmission

- MTCT causes more than a third of all chronic HBV
- Screening for HBsAg during pregnancy:
  - High risk persons only in 1982 (did not work);
  - ACIP recommended universal screening in 1988;
  - Universal Screening recommended by USPST since 2004.
- USA: 25000 infants born from HBsAg(+) mothers
  - If they get infected as neonates, 95% will have chronic HBV

Hepatitis B
Effect of HBV on the Pregnancy

- Prevalence is the same as in general population
- Usually asymptomatic.
- Cirrhosis is uncommon in young childbearing women.
- May increase risk of:
  - perinatal mortality (Safir et al. Liver Intl 2010;30:765-70; Tse KY et al. J Hepatol2005;43:771-5),
  - pre-term birth,
  - low birth weight,
  - gestational diabetes,
  - antepartum hemorrhage

Chronic HBV
Assessment of the Mother

- Laboratory assessment:
  - HBV-DNA Quantitation,
  - HBeAg and anti-HBe,
  - History of past MTCT,
  - HIV or HCV co-infection

  Important in Mother to Child Transmission
  - Liver Enzymes (ALT, AST, T. Bili, Alk. Phosphatase)
  - HBV genotype and HBV mutation status,
  - Family history of Hepatocellular Carcinoma in 1st degree relative,
  - Serology for: Hepatitis D
- Disease stage assessment:
  - Liver biopsy or FibroScan (transient elastography)
    - Usually not done during pregnancy, but can be done post-partum
- Surveillance for HCC by Liver Ultrasound every 6 months (Cirrhosis, African and North American Blacks, 1st degree relative with HCC, Asian female > 50)

Hepatitis B or C and Perinatal Outcome

Safir A et al. Liver Intl 2010;30:765-70

Characteristics	Odds Ratio (OR)	95% CI	p-value	Adjusted OR	95% CI	p-value
Perinatal Mortality	1.8	1.1-2.9	0.016	1.8	1.1-2.9	1.015
Low birth weight (<2.5 kg)	1.4	1.1-1.7	0.009	1.3	1.1-1.7	0.021
Congenital Malformations	1.4	1.1-1.9	0.011	1.4	1.1-1.9	0.012

Chronic Hepatitis B and Hepatitis C increase the risk of Perinatal mortality, low birth weight, and congenital malformations

Hepatitis B
Effect of the Pregnancy on HBV

- Usually disease remains stable and ALT decreases.
- Exacerbation with liver failure is very uncommon.
- Post-partum, one third will have flare up:
  - More frequent in HBeAg(+) than in HBeAg(-).
  - Frequently associated with increased viral load followed with flare at 15-18 weeks post-partum.
  - Flares sometimes lead to viral clearance but are also occasionally severe and fatal.
  - If in short-term antivirals, 50-60% flare up after discontinuation.
  - No clear evidence of decreasing frequency nor severity of flare ups prolonging post-partum antivirals from 4 to 12 weeks (Nguyen V et al. Aliment Pharmacol Ther 2014;39:1225-34).

Hepatitis B
Mother-to-Child Transmission (MTCT)

- Risk of MTCT without Post Exposure Prophylaxis (PEP):
  - HBsAg(+)/HBeAg(-): 2-20%
  - HBsAg(+)/HBeAg(+): 90%
    - HBeAg can pass through the placenta and induces T-cell tolerance facilitating chronic HBV in infant.
  - Post-Exposure Prophylaxis (PEP) is extremely effective if HBV-DNA < 10^6 copies/mL (< 200,000 IU/mL) (Pan CQ et al. Clin Gastroenterol Hepatol 2013;11:1349-55)
- In mother with Acute HBV:
  - Highest MTCT is in 3rd trimester infection (68%)
  - Compared with 1st or 2nd trimester infection (1.8%)
- Pre-embryonic infection can occur (HBV present in sperm, oocytes and embryos)
  - Sperm washing and sperm & embryo cryopreservation may reduce risk.

Maternal HBV Viral Load in HBeAg(+) mothers and Risk of Vertical Transmission with Post Exposure Prophylaxis only

Han et al. AASLD Abstr 170, 2011

< 10^6 copies/mL is < 200,000 IU/mL

PEP is Not-Enough

Viral Load (copies/mL)	**< 10^6**	**10^6 – $10^{6.99}$**	**10^7 – $10^{7.99}$**	**>/= 10^8**
# Mothers	174	298	531	239
# Neonates infected	0	9	29	23
% Neonates Infected	**0**	**3**	**5.5**	**9.6**

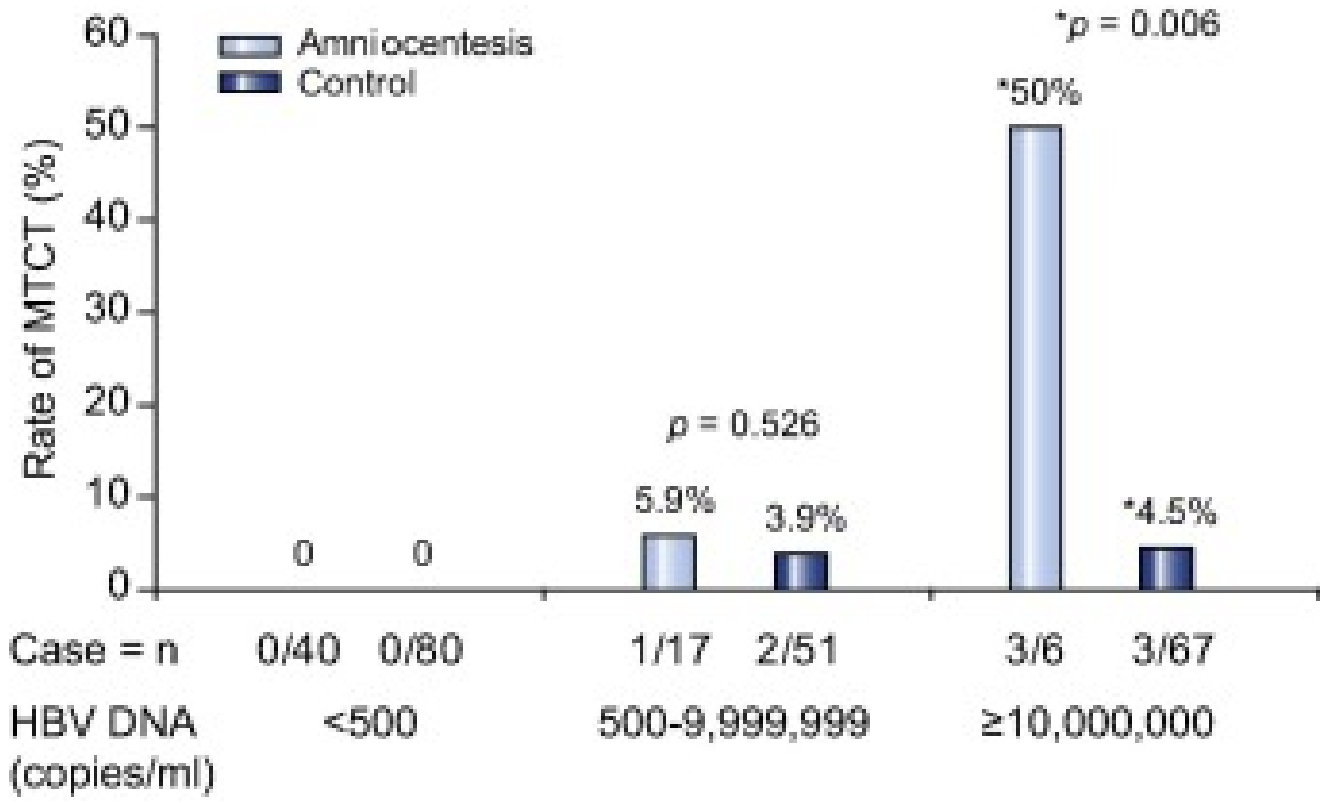
Neonatal Post-Exposure Prophylaxis is not enough when maternal HBV-DNA is 200,000 IU/mL (1,000,000 copies/mL) or more

Hepatitis B
Mother-to-Child Transmission (MTCT)

- Intrauterine transmission is rare (3.7-4%).
- Amniocentesis increases MTCT rate (Yi W et al. J Hepatol 2014;60:523-9), especially if:
  - HBV-DNA >/= 10^7 copies/mL or >/= 2 x 10^6 IU/mL (50% vs 4.5%),
  - HBeAg(+), and
  - When amniocentesis is trans-placental.
- Chorionic villous sampling has higher transmission risk than amniocentesis.

Relation of HBV Viral Load (copies/mL) with Risk of MTC Transmission During Amniocentesis

Yi W et al. J Hepatol 2014;60:523-9



Amniocentesis Increases the Risk of Fetal HBV Infection, specially if maternal HBV-DNA is 10 Million copies/mL or more

Hepatitis B
Predictors of MTCT

- Mode of Delivery:
  - Urgent C-section and vaginal delivery are equivalent
  - Elective C-section has very-small benefit over delivery, when both are used with PEP.
    - Elective C-section is not recommended.
- Breast Feeding:
  - No difference in infection in meta-analysis of breast-fed vs formula-fed infants receiving immune-prophylaxis (Shi Z et al. Arch Pediatr Adolesc Med. 2011 Sep;165(9):837-46.)
    - Breast feeding is encouraged.
  - Tenofovir alafenamide fumarate (TAF) will have even lower levels in milk than TDF (T disoproxil F).
- Genetics: no known effect.
- Bathing:
  - Bathing newborn with mild soap solution, to remove contaminated fluids, might decrease risk.
- Father and siblings with HBV:
  - Vaccination + HBIG (dual post-exposure prophylaxis) decreases horizontal transmission.

Meta-Analysis: Risk of Infant HBV infection in Breastfeeding vs No-breastfeeding
A: Neonatal HBIG + HBV Vaccination
B: Neonatal HBV vaccination only

Shi Z et al. Arch Pediatr Adolesc Med. 2011 Sep;165(9):837-46

HBIG + VACCINE

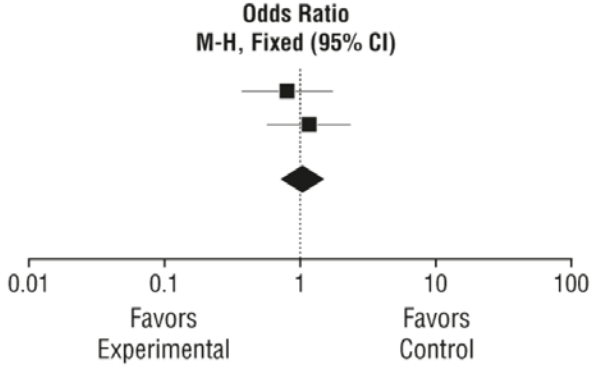
VACCINE ONLY

A

Study or Subgroup	Breastfeeding, No. Events	Breastfeeding, No. Total	Control, No. Events	Control, No. Total	Weight, %	Odds Ratio M-H, Fixed (95% CI)
Zeng et al, 2006	35	70	25	45	50.6	0.80 (0.38-1.70)
Liu et al, 2010	29	61	30	68	49.4	1.15 (0.57-2.30)
Total (95% CI)		**131**		**113**	**100.0**	**0.97 (0.58-1.62)**
Total events	**64**		**55**			

Heterogeneity: $\chi^2_1 = 0.48$ ($P = .49$); $I^2 = 0\%$

Test for overall effect: $Z = 0.11$ ($P = .91$)

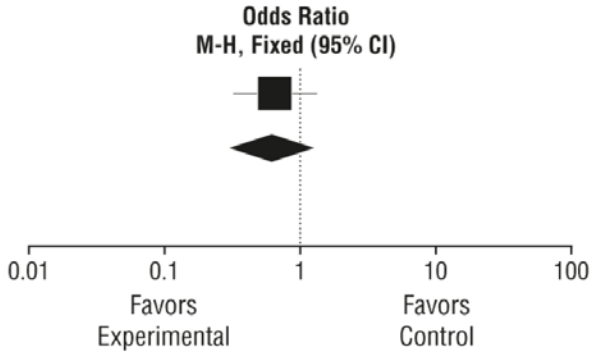


B

Study or Subgroup	Breastfeeding, No. Events	Breastfeeding, No. Total	Control, No. Events	Control, No. Total	Weight, %	Odds Ratio M-H, Fixed (95% CI)
Meng et al, 2004	20	55	37	79	100.0	0.65 (0.32-1.31)
Total (95% CI)		**55**		**79**	**100.0**	**0.65 (0.32-1.31)**
Total events	**20**		**37**			

Heterogeneity: not applicable

Test for overall effect: $Z = 1.20$ ($P = .23$)



In Neonates Receiving HBV Vaccination +/- HBIG, breastfeeding does NOT Increase the risk of HBV infection

Hepatitis B
Methods to Prevent MTCT by Post-Exposure Prophylaxis (PEP)

- HBIG to Newborn:
  - Given within 12 hours from birth
  - Meta-analysis of HBIG at 0, 4-12 and 24 weeks decreases MTCT (OR: 0.5) (mostly HBeAg(+))
- Vaccination of Newborn:
  - Started within 12 hours from birth.
  - Meta-analysis of vaccine at 0, 1, 2, 12 months decrease MTCT with OR: 0.28 (mostly HBeAg(+))
- HBIG to mother + dual Newborn PEP (HBIG + Vaccination):
  - Meta-analysis of maternal HBIG 200 IU IM @ 28, 32, 36 weeks + neonatal dual PEP, decreases intrauterine MTCT in HBeAg (+) and (-) mothers; OR: 0.24 & 0.21 respectively.

Hepatitis B
Methods to Prevent MTCT by Post-Exposure Prophylaxis (PEP)

- Vaccination + HBIG to Newborn (dual PEP):
  - **USA Standard for HBV < 200,000 IU/mL**
  - Meta-analysis shows decrease of MTCT with OR: 0.54 compared with vaccine alone (mostly HBeAg(+)).
  - HBIG and Vaccination start within 12 hours from birth
- Third Trimester Antivirals against HBV + Vaccination +/- HBIG:
  - **USA Standard for HBV > 200,000 IU/mL (with HBIG & vaccine within 12 hours from birth)**
  - Antiviral usually starts at week 28-32 of pregnancy, and ends 4 week post-partum, unless mother has medical indication for continuous therapy.
  - HBIG and Vaccination start within 12 hours from birth.

Vaccination Regimens for Newborn from HBV(+) Mother

- Within 12 hours of birth:
  - Single Antigen vaccine (not counted in “true vaccination” schedule) +
  - Hepatitis B Immune Globulin (HBIG) (0.5 mL IM in the anterolateral thigh), followed by “true vaccination”.
- Single Antigen Hepatitis B Vaccine:
  - Recombivax HB or Egerix B: 1, 2, and 6 months, or
- Combination Antigen Vaccines:
  - Pediarix (diphtheria, tetanus toxoids, acellular pertussis adsorbed, hepatitis b and inactivated poliovirus): 2, 4 and 6 months, or
  - Comvax (Haemophilus B + Hepatitis B): 2, 4, and 12 months.
- Test for Response:
  - HBsAg and anti-HBs titer at age 9-15 months, but not before 4 to 8 weeks after last vaccination.
  - Protective titers are > 10 IU/mL (best if > 100 IU/mL)
  - If titer < 10 IU/mL, a second 3-dose series should be offered.

Hepatitis B
Prevention of MTCT by Antivirals + Post-Exposure Prophylaxis (PEP)

- **INDICATION:** Mothers with HBV-DNA > 1 million copies/mL or 200,000 IU/mL

- **REGIMEN:** antivirals starting @ week 28-32, until 0-12 (usually 4) weeks post-partum + newborn vaccination or dual PEP (HBIG + Vaccination is the standard in USA).
  - Lamivudine decreased MTCT with OR: 0.31 @ 6-12 months
  - Telbivudine decreased MTCT with OR: 0.13 @ 6-12 months
  - Tenofovir decreased MTCT with OR: 0.22 @ 6-12 months

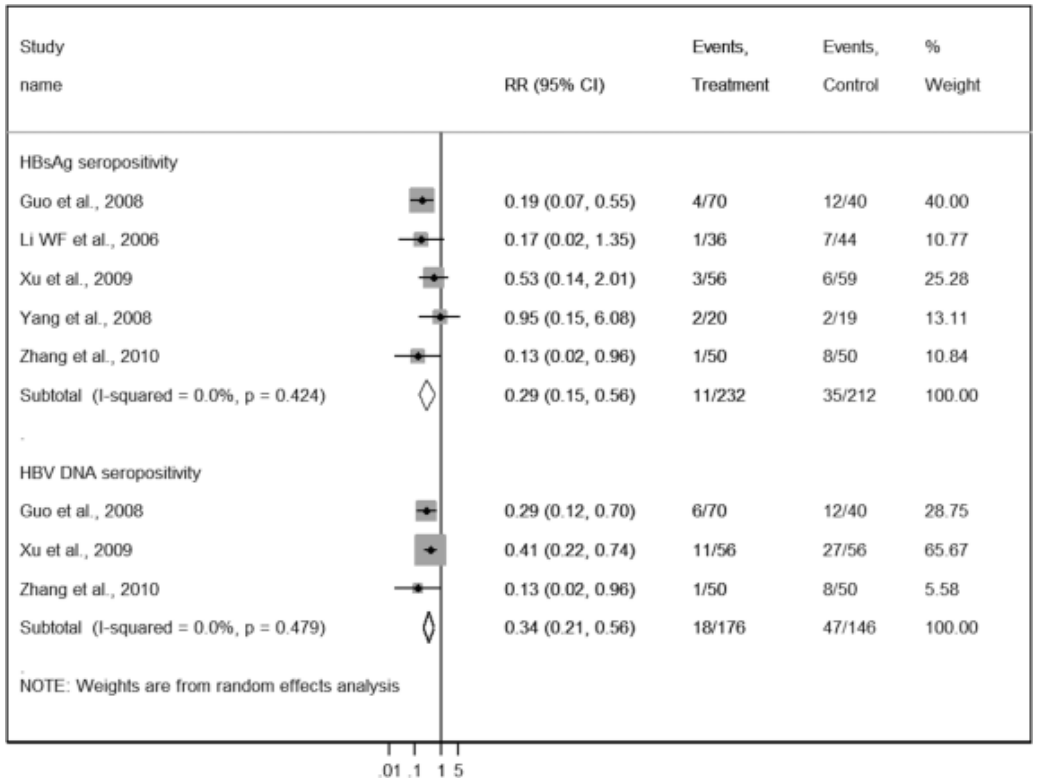
Hepatitis B
Prevention of MTCT by Antivirals + Post-Exposure Prophylaxis (PEP)

- **Choice of Antiviral:**
  - Mother HBV mono-infected and in need of therapy:
    - Tenofovir (category B).
  - Mother HBV mono-infected but without need of therapy other than MTCT:
    - Tenofovir (cat B; preferred agent),
    - Telbivudine (cat B), or
    - Lamivudine (cat C) (only if HBV-DNA is < 2 x 10^7 IU/mL before therapy; (Han L et al. World J Gastroenterol 2011;17:4231-33)
  - Mother with HIV co-infection, in need or not of HBV therapy, but not on HAART:
    - Telbivudine (cat B)
  - Mother with HIV co-infection and in HAART:
    - Tenofovir alafenamide fumarate (TAF) (cat B) as part of HAART
    - Whole-body bone mineral content of Tenofovir exposed infants born to HIV-infected mothers was 12% lower than for unexposed infants.

Effect of Maternal Antiviral Therapy in MTC HBV Transmission at 6-12 months: Meta-Analysis

Brown RS et al. Hepatology 63(1): 319-33; 2016

Any Antiviral vs Control



Study name	RR (95% CI)	Events, Treatment	Events, Control	% Weight
HBsAg seropositivity				
Guo et al., 2008	0.19 (0.07, 0.55)	4/70	12/40	40.00
Li WF et al., 2006	0.17 (0.02, 1.35)	1/36	7/44	10.77
Xu et al., 2009	0.53 (0.14, 2.01)	3/56	6/59	25.28
Yang et al., 2008	0.95 (0.15, 6.08)	2/20	2/19	13.11
Zhang et al., 2010	0.13 (0.02, 0.96)	1/50	8/50	10.84
Subtotal (I-squared = 0.0%, p = 0.424)	0.29 (0.15, 0.56)	11/232	35/212	100.00
HBV DNA seropositivity				
Guo et al., 2008	0.29 (0.12, 0.70)	6/70	12/40	28.75
Xu et al., 2009	0.41 (0.22, 0.74)	11/56	27/56	65.67
Zhang et al., 2010	0.13 (0.02, 0.96)	1/50	8/50	5.58
Subtotal (I-squared = 0.0%, p = 0.479)	0.34 (0.21, 0.56)	18/176	47/146	100.00

NOTE: Weights are from random effects analysis

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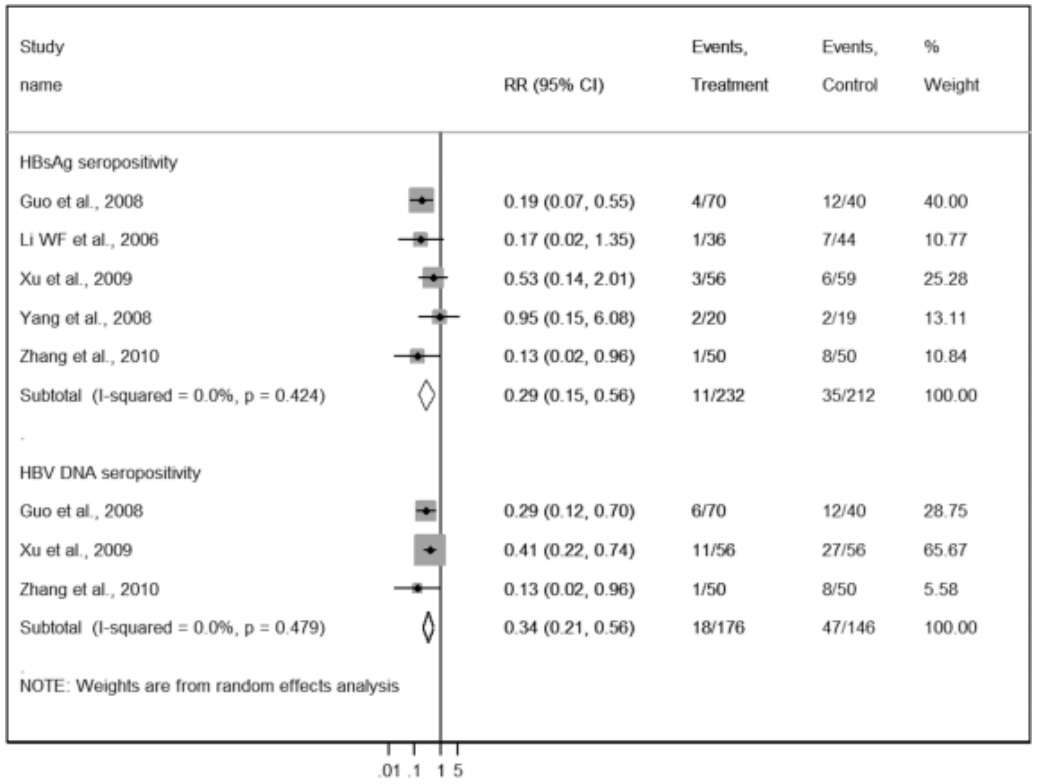
Lamivudine vs Control



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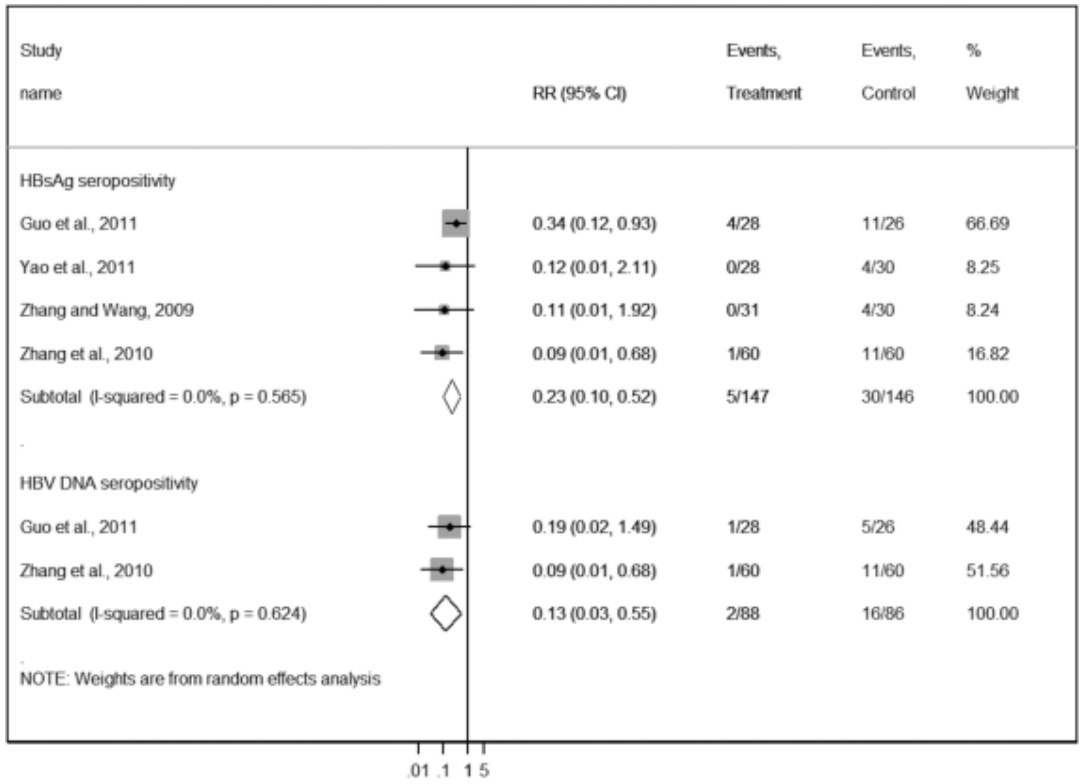
Antiviral Therapy Decreases HBV Transmission to the Neonate

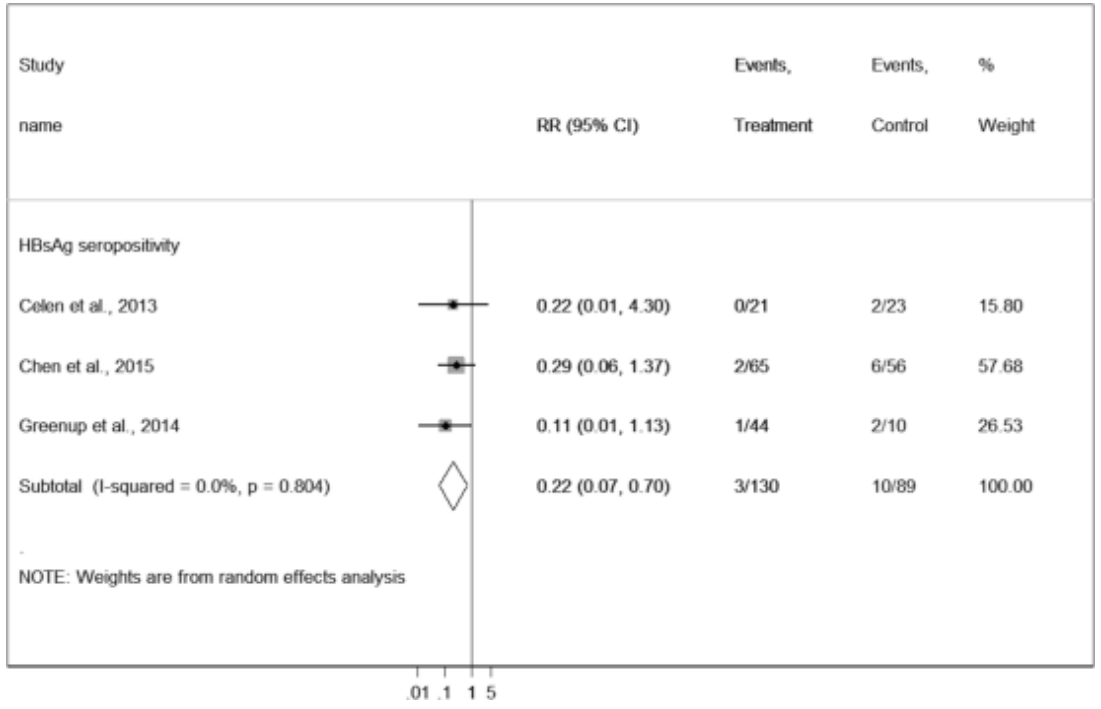
Effect of Maternal Antiviral Therapy in MTC HBV Transmission at 6-12 months: Meta-Analysis

Brown RS et al. Hepatology 63(1): 319-33; 2016

Telbivudine vs Control



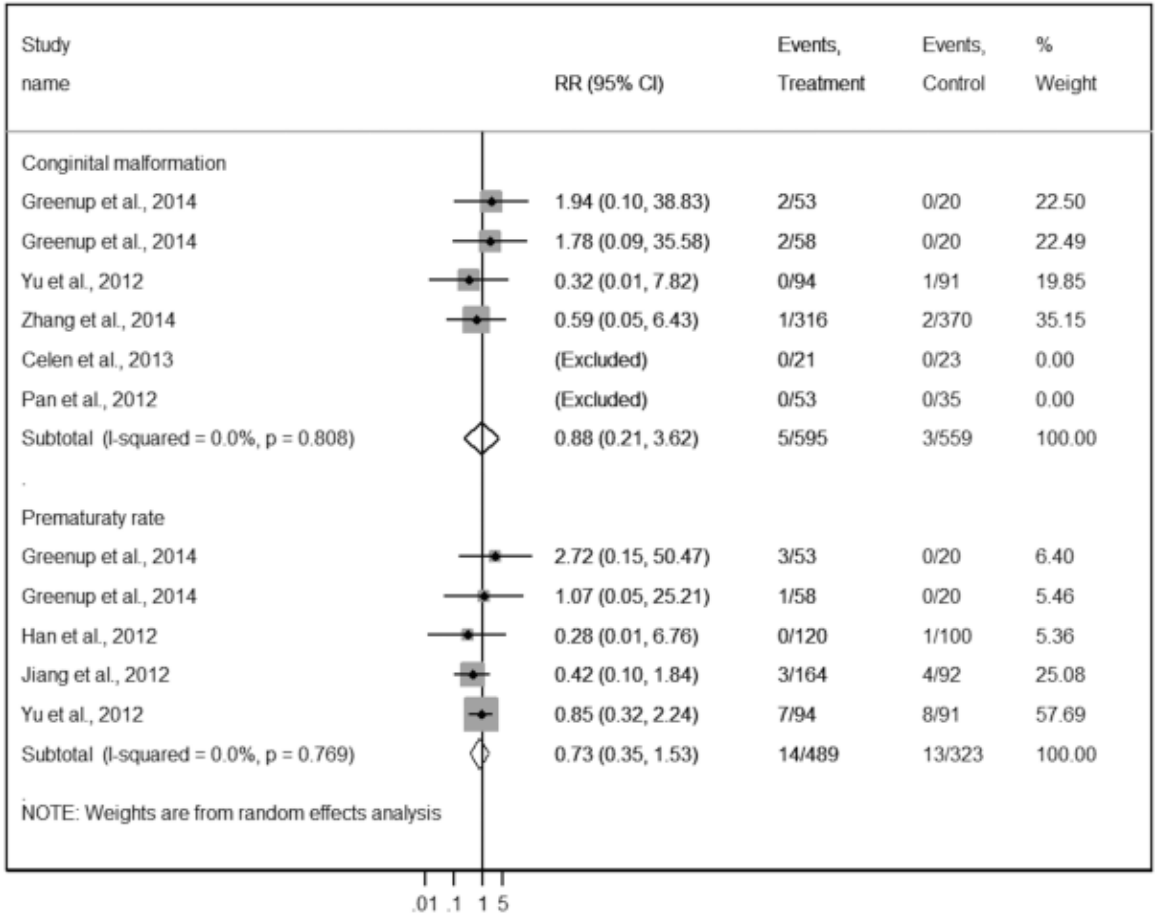
Tenofovir vs Control



Antiviral Therapy Decreases HBV Transmission to the Neonate

Meta-Analysis: Congenital Malformations and Prematurity in Maternal HBV Therapy vs Control

Brown RS et al. Hepatology 63(1): 319-33; 2016



HBV Antiviral Therapy Does NOT Increase the Rate of Congenital Malformations nor of Prematurity

Hepatitis B
Prevention of MTCT by Antivirals + Post-Exposure Prophylaxis (PEP)

- **MONITORING:**
  - Mother should be monitored for post-partum flare for at least 6 months, if antiviral therapy is discontinued or not given.
  - Mother should have regular HBV control follow up if the treatment was indicated due to mother condition
    - Cirrhosis, or
    - Elevated ALT + HBV-DNA > 2000 IU/mL in HBeAg(-) or HBV-DNA > 20000 IU/mL in HBsAg(+))
  - Mother with risk of liver cancer should be under surveillance with liver ultrasound every 6 months.
  - Child should be checked at age 9-15 months (4-8 weeks after final vaccine) for HBsAg and antibody titer.
    - If child is infected, over a follow up of up to 29 years, up to 2% may develop HCC (Bortoletti et al. Hepatology 2006;43:556-62)

Conclusion

- Testing for HBV should be routine in every pregnancy and before amniocentesis or villous sampling.
- If Hepatitis B is present, a complete evaluation of the patient should follow.
- Neonates with mothers infected with HBV should receive post exposure prophylaxis, starting within 12 hour from birth, and followed by a complete cycle of HBV vaccination and post-vaccination testing.
- If the mother HBV viral load is >/= 200,000 IU/mL, she should receive antiviral therapy to decrease the risk of vertical transmission.
- The choice of agent will depend on: need for the mother for therapy, presence of HIV infection, and presence of anti-HIV HAART therapy.
- The HBV(+) mother should be watch for 6 months after delivery, for flare up of her infection.

Hepatitis C

Hepatitis C
Extent of the Problem

- 2-3% of world population is or has been infected
  - 170 Million (75% with viremia)
  - 3-4 Million new infections per year
  - 350,000 deaths per year
- Prevalence:
  - 1.8-5% in underdeveloped world
    - Blood product & Medical interventions or equipment
  - 0.05-0.36% in developed world
  - Pediatric Infections in USA:
    - MTCT (60-90%) & Needle sharing (in adolescents)
    - anti-HCV(+) in 0.17% of age 6-11, and 0.39% of age 12-19 (NHANES III)
- 11 Million below age 15
  - 5 Million with viremia

Hepatitis C
Effect of Pregnancy

- Prevalence in pregnancy is the same as in general population
- Usually asymptomatic
- May increase risk of Intrahepatic Cholestasis of Pregnancy
- Possible increase in pre-term delivery and low birth weight
- Viral load increases and ALT decreases during pregnancy
  - down-regulation of T-cell mediated reactivity and
  - increase in regulatory T-cells activity during pregnancy
- Post partum decrease in viral load and increase in ALT
  - increased T-cell cytotoxicity post partum

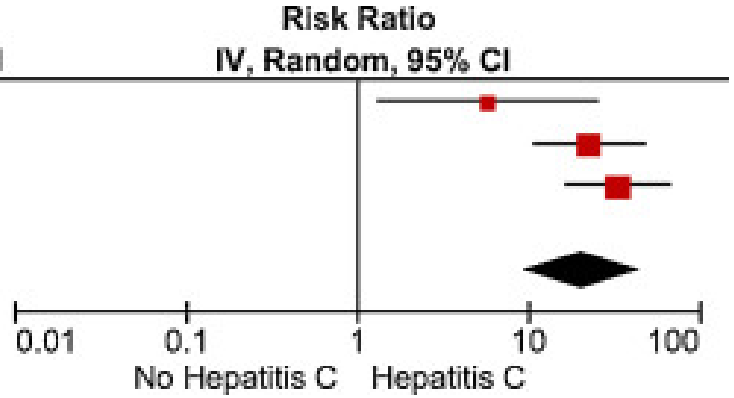
HCV and Intrahepatic Cholestasis of Pregnancy: A Systematic Review and Meta-analysis

Wijarnpreecha K et al. Clin Res Hepatol Gastroenterol Aug 16, 2016

Study or Subgroup	log[Risk Ratio]	SE	Weight	Risk Ratio IV, Random, 95% CI
Marschall et al	1.750937	0.758663	19.0%	5.76 [1.30, 25.48]
Locatelli et al	3.109061	0.383693	39.5%	22.40 [10.56, 47.52]
Paternoster et al	3.505257	0.357134	41.5%	33.29 [16.53, 67.04]
Total (95% CI)			**100.0%**	**20.40 [9.39, 44.33]**

Heterogeneity: $Tau^2 = 0.25$; $Chi^2 = 4.40$, df = 2 (P = 0.11); $I^2 = 55\%$

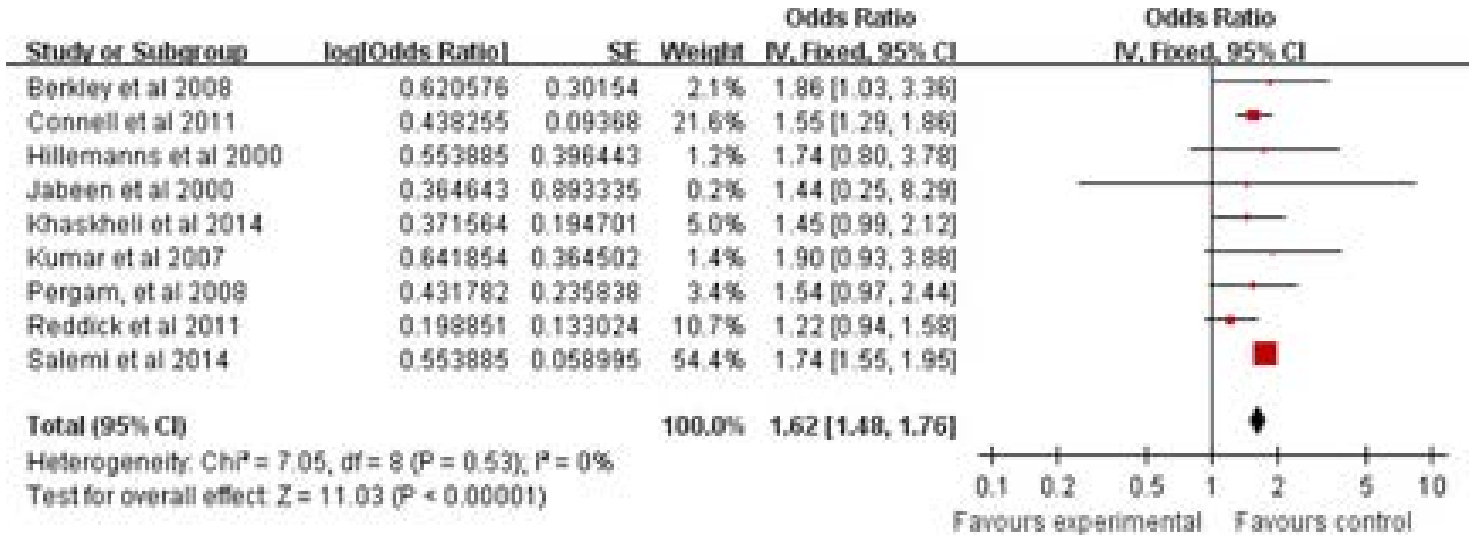
Test for overall effect: Z = 7.62 (P < 0.00001)



HCV Infection Increases the Risk of Intrahepatic Cholestasis of Pregnancy

Meta-analysis of Observational Studies: HCV and Risk of Preterm Birth

Huang Q-t et al. J of Viral Hepatitis 2015; 22:1033-1042



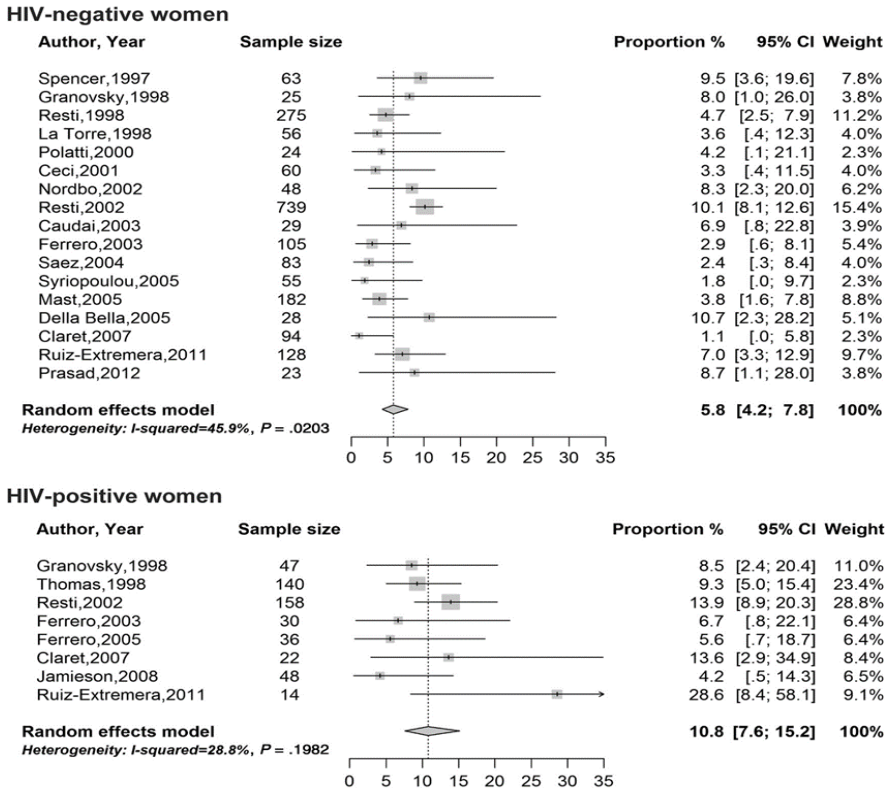
Chronic HCV increases the risk of Preterm Birth

Hepatitis C
Mother-to-Child Transmission (MTCT)

- Risk of MTCT is 3-10% (mean 5%)
  - 5.8% in HCV-RNA(+)/HIV(-) mother
  - 10.8% in HCV-RNA(+)/HIV(+) mother
  - Passive transmission of maternal antibodies lasting >/= 12 months gives false positives
- Placental cells can get infected
- Increased NK and NK T cells in placenta could clear the virus
  - Infected maternal cell can pass placenta without causing infection but giving exposure to fetus, causing antibody formation.

Vertical Transmission of Hepatitis C Virus: Systematic Review and Meta-analysis

Benova L et al. Clin Infec Dis 2014; 59:765-73



The Risk of MTCT of HCV is Higher in mothers with HCV/HIV (10.8%) than in HCV (5.8%)

Hepatitis C
Mother-to-Child Transmission (MTCT)

- Any genotype can be transmitted
  - Only some quasispecies infect the child, even if not dominant in the mother.
  - The infecting quasispecies have optimized replicative fitness.
- Only 30% of infected neonates will have viremia at day 3 (in utero infection).
  - The other 70% will have viremia by month 3 (peri-partum infection).
- Breast feeding and mode of delivery have minimal effect in MTCT.

Hepatitis C
Predictors of MTCT

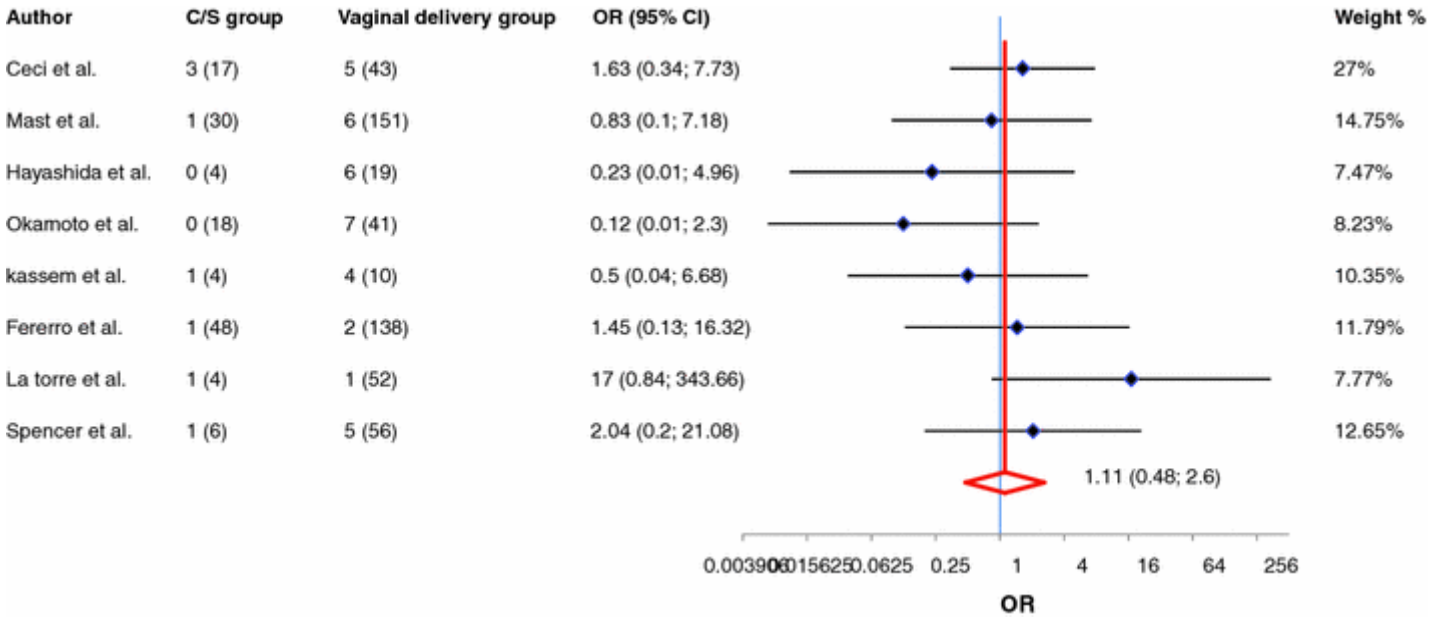
- Maternal HCV factors:
  - Positive correlation with viral load but no ”threshold value”.
    - Great overlap of values.
  - HCV can replicate in PBMCs
    - Frequency of HCV-RNA in PBMCs correlates with MTCT.
  - Maternal IVDA increases viral load in PBMCs and infection rate.
- Mother HIV/HCV coinfection:
  - Most important co-factor for HCV MTCT (OR: 2.56).
  - Treatment with HAART eliminates MTCT risk-difference.
  - HIV and HCV are transmitted independently.

Hepatitis C
Predictors of MTCT

- Obstetric Factors:
  - HCV-RNA present in amniotic fluid.
  - Amniocentesis may increases risk of MTCT.
  - Internal Fetal monitoring increases risk of MTCT.
  - Perineal and vaginal laceration increases risk but episiotomy does not.
  - Rupture of membranes > 6 h correlates with risk.
  - Higher risk for female neonates
- Mode of Delivery:
  - Large observational studies & meta-analysis do not show correlation.
  - No enough data looking at pre-delivery viral load.

Effect of Cesarean Section on the Risk of Perinatal Transmission of HCV: A Meta-Analysis

Ghamar C et al. Arch Gynecol Obstet 2011; 283:255-60



Cesarean Section Does NOT Decrease MTCT of HCV in HIV(-) Mothers, compared to Vaginal Delivery

Hepatitis C
Predictors of MTCT

- Breast feeding:
  - Most studies did not find correlation (Polywka S et al. Clin Infect Dis 1999; 29:1327).
  - Risk may increase in bleeding or cracked nipples (CDC).
  - Breast milk has endogenous generation of free fatty acids that destroy the viral lipid envelope (Plaender S et al. JID 2013;208:1943-52).
- Genetics:
  - Mother-child HLA concordance facilitates MTCT.
  - Mismatch of HLA-DRB1 is protective.
  - Maternal HLA-DRB104 is protective.
  - Neonatal HLA-DRB110 increases risk.
  - IL-28B polymorphism has no effect.
  - Cytokines: gene polymorphism of TNF, IFN-gamma, IL-1, TGF-B1 has no effect.
- Father with HCV infection increase risk

Hepatitis C
Manifestations and Evolution of HCV in Children

- Manifestations of Primary infection:
  - Usually asymptomatic.
  - ALT may be normal or elevated.
  - Viremia is usually anti-HCV(+); very rarely antibody(-).
  - Testing with anti-HCV and HCV-RNA should NOT be done before 18 months of age.
- Spontaneous Viral Clearance (SVC) in Children:
  - 20% @5y; 27% @10y.
  - Most spontaneous clearance is done by age 7.
  - More common if:
    - ALT is high in first 2 years,
    - in genotype 3, and
    - in IL-28B rs 12979860 C/C group (OR: 2.7).
  - Higher SVC in post-transfusion HCV (27%) than in MTCT (9%).

Hepatitis C
Manifestations and Evolution of HCV in Children

- Chronic Hepatitis:
  - Usually milder than in adults;
  - Cirrhosis is infrequent.
  - HCC is extremely rare.
  - Growth in weight & height is not affected.
  - May have cryoglobulins and develop MPGN.
  - Increase risk of thyroid disease.

Prevention of HCV MTCT

- Treat HCV before Pregnancy.
  - If Ribavirin was given, wait 6 months before conception.
- In HIV/HCV Co-infection, HAART decreases HCV MTCT to rates similar to those seen with HCV mono-infected mothers. Give HAART.
- Avoid amniocentesis, specially trans-placental.
- Avoid chorionic villous sampling
- Avoid Internal Fetal Monitoring

Prevention of HCV MTCT

- Avoid perineal and vaginal laceration.
- Keep rupture of membranes < 6 hours before delivery
- There are no studies to decrease MTCT with new HCV Direct-Antiviral Agents during pregnancy.
  - Category B: Viekira Pack, Viekira XR, Harvoni, Epclusa, Simeprevir, Sofosbuvir
  - Category C: Peg-Interferon
  - Not Assigned: Zepatier, Daclatasvir
  - Category X: Ribavirin is highly teratogenic
- TESTING: Child should not be tested before 18 months of age.

Thank you for your attention,

Questions?