“Strategies for Timely Completion on Hepatitis B Series Dose and Post Vaccine Serology Testing,”

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Goals

- Review current recommendations for Hepatitis B vaccine and discuss strategies how to improve in Texas
- Review current recommendations for Post Vaccine serological testing and discuss resources to use nationally and in Texas
She has been with her adoptive family for 5 weeks in USA.
Abandoned at an outpatient medical facility at 6 months lived in Children’s Welfare Institute Zhongshan China.
Screening labs at 22 months of age positive for Hepatitis B, for which she was receiving herbal supplements and also had a congenital heart disease a VSD.
2.5 year old adopted Chinese female

- Physical exam normal except for heart murmur consistent with a VSD
- Hepatitis B quantitative DNA 77.4 million
  - Hepatitis Be antigen reactive
  - Hepatitis B core antibody IgG reactive
  - Hepatitis A, Hepatitis C, Syphilis and HIV negative
  - HBV genotype B no mutations detected
  - Liver enzymes normal (ALT 45 and AST 52)
2.5 year old adopted Chinese female

- Received Hepatitis A vaccine series and has been followed for 2 years
- Yearly AFP and abdominal US have been normal and liver enzymes have remained under 50.
- Had surgical correction of her VSD at 3.5 years
- Her Hepatitis B DNA quantitative has risen to greater than 170 million.
This electron micrograph reveals the presence of hepatitis B virus (HBV) or Dane particles. Infectious HBV virions are also known as Dane particles. These particles measure 42 nm in their overall diameter and contain a DNA-based core that is 27 nm in diameter. Courtesy of Centers for Disease Control and Prevention
Section of liver damaged by hepatitis B virus. Note the enlarged cells and blistering of the capsular surface. Courtesy of Immunization Action Coalition
This female Cambodian patient presented with a distended abdomen due to a hepatoma resulting from chronic hepatitis B infection. Courtesy of Centers for Disease Control and Prevention
Routine hepatitis B immunization programs have resulted in significant decreases in the prevalence of chronic HBV infection among children in populations with a high incidence of HBV infection.

There is an association between higher coverage with HepB vaccine and larger decreases in HBsAg prevalence.

The incidence of acute HBV infection among US children younger than 19 years decreased by 98% between 1990 and 2010.
FIGURE. Rate* of reported acute hepatitis B among children aged 1–9 years and percentage of children aged 19–35 months who received hepatitis B vaccine, by year — United States, 1986–2000

* Per 100,000 children aged 1–9 years.
Perinatal transmission of HBV is highly efficient and usually occurs from blood exposures during labor and delivery.

In utero transmission accounts for less than 2% of all vertically transmitted HBV infections in most studies.

Without postexposure prophylaxis, the risk of an infant acquiring HBV from an infected mother as a result of perinatal exposure is 70% to 90% for infants born to mothers who are HBsAg and HBeAg positive.

The risk is 5% to 20% for infants born to HBsAg-positive but HBeAg-negative mothers.
Although the long-term sequelae of chronic HBV infection usually are not recognized until adolescence and adulthood, cirrhosis and HCC occur in children.

In Taiwan, the average annual incidence of HCC among children 6 to 14 years of age decreased significantly within 10 years of routine infant hepatitis B immunization.

Worldwide, routine infant immunization programs and introduction of immunization schedules starting within the first 24 hours of life are expected to decrease significantly the incidence of death from cirrhosis and HCC attributable to HBV infection over the next 30 to 50 years.
“Strategies for Timely Completion on Hepatitis B Series Dose"
Many infants in the United States are not receiving the birth dose of hepatitis B vaccine.

- Only 74.2% of U.S. infants received hepatitis B vaccine within 3 days of birth.*
- States’ coverage rates varied between 44.8% and 88.0%.*

There is room for improvement in protecting newborn infants in every state.

*Reference: Data from 2013 National Immunization Survey, at www.cdc.gov/mmwr/preview/mmwrhtml/mm6334a1.htm
Hepatitis B vaccine
Why should we give hepatitis B vaccine to all newborns?

- **Prevents mother-to-infant transmission:** Prevents 70–95% of infection among infants born to HBsAg-positive women

- **Prevents household transmission:** Protects infants from infected family members and other caregivers

- **Protects when medical errors occur:** Provides a safety net to prevent perinatal HBV infection when medical errors occur
Types of medical errors reported

- Ordering the wrong hepatitis B screening test
- Misinterpreting or mistranscribing the hepatitis B test results
- Failing to communicate the HBsAg test results to or within the hospital
- Not giving hepatitis B vaccine to infants born to mothers of unknown HBsAg status within 12 hours of birth
- Not giving prophylaxis to an infant even when the mother’s HBsAg-positive status is documented
Give birth to the end of Hep B

An IAC initiative to eliminate hepatitis B virus infection in the U.S. through the prevention of perinatal transmission
Hepatitis B birth dose is recommended by ACIP, AAP, AAFP, and ACOG

“Administer monovalent Hep B vaccine to all newborns before hospital discharge.”

1. Executive Summary – What Hospitals Need to Do to Protect Newborns

2. National Quality Forum (NQF) has established newborn hepatitis B vaccination as a national standard for measurement by healthcare settings
Birthing facilities play a critical role in preventing chronic hepatitis B infections through timely initiation of post-exposure prophylaxis, and by creating a birth dose safety net for eliminating perinatal hepatitis B transmission.

The most important steps for birthing facilities to take are:

- Implement a universal birth dose policy
- Ensure universal review of the original maternal HBsAg test results
- Implement standard admission orders for timely administration of hepatitis B vaccine to all newborn infants
- Follow national recommendations for prophylaxis of newborn infants

- Infants born to women with HBsAg-positive test results and
- Infants born to women whose HBsAg status is unknown

Complete 2005 ACIP Recommendations are available at www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
Two Tools for Promoting the Hepatitis B Birth Dose

- “Hepatitis B: What Hospitals Need to Do to Protect Newborns” – a comprehensive guide
- Hepatitis B Birth Dose Honor Roll

www.immunize.org/protect-newborns
Texas Births 2013

- Births 387,110
- Hospital 382,081 98.7%
- Home or other 5,029 1.3%
- Attendant Physician 95.3%
- Other 4.7%
How many hospitals in Texas give over 90% birth HBV vaccine at birth

- 36
- 583 hospitals in Texas
Big Bend Medical Center, Alpine, TX
Reported a coverage rate of 97% from 2/1/15 to 1/31/16

Brownfield Regional Medical Center, Brownfield, TX
Reported a coverage rate of 93% from 1/1/15 to 12/31/15

BSA Health System, Amarillo, TX
Reported a coverage rate of 99% from 1/1/14 to 12/31/15 and 95% from 1/1/15 to 12/31/15

CHI St. Luke’s Health-Memorial Lufkin, TX
Reported a coverage rate of 97% from 7/1/14 to 6/30/15

Childress Regional Medical Center, Childress, TX
Reported a coverage rate of 99% from 1/1/14 to 12/31/14

Christus St. Michael Health System, Texarkana, TX
Reported a coverage rate of 96% from 5/1/15 to 4/30/16

Columbus Community Hospital, Columbus, TX
Reported a coverage rate of 99% from 5/1/15 to 4/30/16

Del Sol Medical Center, El Paso, TX
Reported a coverage rate of 99% from 8/1/12 to 7/31/13

Golden Plains Community Hospital, Borger, TX
Reported a coverage rate of 98% from 1/1/13 to 12/31/13 and 99% from 1/1/14 to 12/31/14

Hereford Regional Medical Center, Hereford, TX
Reported a coverage rate of 100% from 11/1/12 to 11/1/13

The Hospitals of Providence-East Campus, El Paso, TX
Reported a coverage rate of 99% from 1/1/15 to 12/31/15
The Hospitals of Providence-Memorial Campus, El Paso, TX
Reported a coverage rate of 97% from 1/1/15 to 1/1/16

The Hospitals of Providence-Sierra Campus, El Paso, TX
Reported a coverage rate of 100% from 1/1/15 to 12/31/15

Houston Methodist Sugarland Hospital, Sugarland, TX
Reported a coverage rate of 99% from 1/1/15 to 12/31/15

Lamb Healthcare Center, Littlefield, TX
Reported a coverage rate of 94% from 1/1/15 to 12/31/15

Las Palmas Medical Center, El Paso, TX
Reported a coverage rate of 99% from 4/1/15 to 4/1/16

Medical Arts Hospital, Lamesa, TX
Reported a coverage rate of 95% from 1/1/15 to 12/31/15

Medical Arts Hospital, Odessa, TX
Reported a coverage rate of 95% from 5/15/15 to 5/15/16

Medical Center Hospital, Odessa, TX
Reported a coverage rate of 95% from 5/15/15 to 5/15/16

Methodist Dallas Medical Center, Dallas, TX
Reported a coverage rate of 96% from 1/1/13 to 12/31/13

Midland Memorial Hospital Midland, TX
Reported a coverage rate of 90% from 1/1/15 to 12/31/15

Moore County Hospital District, Dumas, TX
Reported a coverage rate of 95% from 1/1/15 to 12/31/15
Nacogdoches Medical Center, Nacogdoches, TX
Reported a coverage rate of 98% from 1/1/15 to 12/31/15

Ochiltree General Hospital, Perryton, TX
Reported a coverage rate of 99% from 1/1/14 to 12/31/14

Olney Hamilton Hospital, Olney, TX
Reported a coverage rate of 97% from 1/1/13 to 12/31/13 and 100% from 1/1/14 to 12/31/14 and 96% from 1/1/15 to 12/31/15

Pal Pinto General Hospital, Mineral Wells, TX
Reported a coverage rate of 99% from 1/1/13 to 12/31/13 and 98% from 1/1/14 to 12/31/14

Pampa Regional Medical Center, Pampa, TX
Reported a coverage rate of 98% from 11/1/12 to 11/1/13

Pecos County Memorial Hospital, Fort Stockton, TX
Reported a coverage rate of 98% from 12/18/12 to 12/18/13

Reeves County Hospital District, Pecos, TX
Reported a coverage rate of 94% from 1/1/14 to 12/31/14

Rio Grande Regional Hospital, McAllen, TX
Reported a coverage rate of 96% from 1/1/15 to 12/31/15

Scenic Mountain Medical Center, Big Spring, TX
Reported a coverage rate of 96% from 1/1/15 to 12/31/15
Seminole Memorial Hospital, Seminole, TX
Reported a coverage rate of 92% from 1/1/15 to 12/31/15

Shannon Medical Center, San Angelo, TX
Reported a coverage rate of 97% from 1/1/15 to 12/31/15

St. David's Georgetown Hospital, Georgetown, TX
Reported a coverage rate of 93% from 1/1/15 to 12/31/15

St. David's Round Rock Medical Center, Round Rock, TX
Reported a coverage rate of 93% from 1/1/15 to 12/31/15

Texas Health Presbyterian Hospital, Rockwall, TX
Reported a coverage rate of 93% from 12/1/12 to 12/31/15

Yoakum County Hospital, Denver, TX
Reported a coverage rate of 92% from 1/1/15 to 12/31/15
Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2016.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Birth</th>
<th>1 mos</th>
<th>2 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>15 mos</th>
<th>18 mos</th>
<th>18-23 mos</th>
<th>2-3 yrs</th>
<th>4-6 yrs</th>
<th>7-10 yrs</th>
<th>11-15 yrs</th>
<th>16-18 yrs</th>
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<tbody>
<tr>
<td>Hepatitis A (HPV)</td>
<td>1st</td>
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<td>Rotavirus (RV, titer)</td>
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<td>2nd</td>
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<td>Diphtheria, tetanus, and cellular pertussis (DTP)</td>
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<td>Measles, mumps, rubella (MMR)</td>
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<td>Varicella (VZV)</td>
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<td>Hepatitis A titer (HepA)</td>
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<td>Haemophilus influenzae type b (Hib)</td>
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<td>Pneumococcal conjugate vaccine (PPV13)</td>
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<td>Inactivated poliovirus vaccine (IPV)</td>
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<td>Influenza (B): LAI</td>
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<td>Measles, mumps, rubella (MMR)</td>
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<td>Varicella (VZV)</td>
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<td>Haemophilus influenzae type b (Hib)</td>
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<td>Tetanus, diphtheria, and pertussis (Td, 4-6 mos)</td>
<td>1st</td>
<td>2nd</td>
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<td>Human papillomavirus (HPV)</td>
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<td>Meningococcal B</td>
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<tr>
<td>Pneumococcal polysaccharide (PPS)</td>
<td>1st</td>
<td>2nd</td>
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</table>

Range of recommended ages for each vaccine is also provided. This schedule includes recommendations in effect as of January 1, 2016. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed instructions, available online at http://www.cdc.gov/vaccines/acip/visit/child/index.html. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (http://www.vaers.hhs.gov) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (http://www.cdc.gov/vaccines/safe/administrations.html) or by telephone (800-325-4610). This schedule is approved by the Advisory Committee on Immunization Practices (http://www.cdc.gov/vaccines/acip/index.html), the American Academy of Pediatrics (http://www.aap.org), the American Academy of Family Physicians (http://www.aafp.org), and the American College of Obstetricians and Gynecologists (http://www.acog.org).

NOTE: The above recommendations must be read along with the footnotes of this schedule.
“Strategies for Timely Completion on Hepatitis B Series Dose”

- Birth
- 1-2 months Other immunizations at 2 months
- 6-18 months Other immunizations at 4, 6, 9, 12, 15, 18 months
- For 2\textsuperscript{nd} and 3\textsuperscript{rd} shots MEDICAL HOME!
No post vaccine serology testing for infants born to Hepatitis B surface antigen negative mothers
Post Vaccination Serological Testing of infants born to Hepatitis B-infected mothers

- MMWR recommended PVST at 9-18 months in 2005 or 1 month after the last dose if delayed

- PVST is 2 tests
  - HBsAG
  - AntiHBs;
  - MMWR in 2015 recommended PVST at 9-12 months or 1-2 months after vaccine series if delayed because combination vaccine formally given was discontinued and new data from Enhanced Perinatal Hepatitis B Prevention Program
Post Vaccination Serological Testing of infants born to Hepatitis B-infected mothers

- 25,000 infants born to HBsAg positive mothers in US
- 40-90% develop chronic infection
- 25% of them will die prematurely from cirrhosis or liver cancer
Post Vaccination Serological Testing of infants born to Hepatitis B-infected mothers

- Vaccine responder/protected if no HBsAg detected and AntiHBs levels > 10 mIU/ml
- HBV infected if HBsAg positive and Anti HBs negative, positive or not done
- Susceptible if AntiHBs negative and HBsAg negative (second 3 dose series with repeat testing one month after)
Post Vaccination Serological Testing of infants born to Hepatitis B-infected mothers

- Post vaccination seroprotection in 98%
- Lower in infants with birth weight of <2000 g (<4.4lbs)
- Anti HBs levels after vaccination decline over time
  however
- Immunocompetent persons who achieve an Anti HBs level of >10mIU/mL remain protected even if anti HBs levels decline to < 10 mIU/mL.
Proportion of infants with anti-HBs ≥10 mIU/mL with increasing interval from final vaccine dose*
Post Vaccination Serological Testing of infants born to Hepatitis B-infected mothers

- Persistent cellular immunity explanation
- No earlier than 9 months to avoid detection of passive anti-HBs from hepatitis b immune globulin administered at birth and to maximize likelihood of detecting late HBV infection
- Test results for HBsAg can be transiently positive for 1-18 days after vaccination
### TABLE 3. Postvaccination serologic testing (PVST) among infants who received $\geq$3 doses of HepB by age 24 months (N = 4,214) — Enhanced Perinatal Case Management Project, Florida, Michigan, Minnesota, New York City, and Texas, 2008–2011

<table>
<thead>
<tr>
<th>PVST status</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reported serologic markers tested</strong></td>
<td></td>
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</tr>
<tr>
<td>Anti-HBs and HBsAg*</td>
<td>2,832</td>
<td>(67.2)</td>
</tr>
<tr>
<td>Anti-HBs only</td>
<td>41</td>
<td>(1.0)</td>
</tr>
<tr>
<td>HBsAg only</td>
<td>371</td>
<td>(8.8)</td>
</tr>
<tr>
<td><strong>Reported serologic testing (by age)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;9 mos</td>
<td>259</td>
<td>(6.2)</td>
</tr>
<tr>
<td>9–12 mos</td>
<td>1,204</td>
<td>(28.5)</td>
</tr>
<tr>
<td>13–18 mos</td>
<td>869</td>
<td>(20.6)</td>
</tr>
<tr>
<td>$\geq$19 mos</td>
<td>351</td>
<td>(8.4)</td>
</tr>
<tr>
<td>Unknown†</td>
<td>561</td>
<td>(13.3)</td>
</tr>
<tr>
<td><strong>No reported PVST</strong></td>
<td>970</td>
<td>(23.0)</td>
</tr>
</tbody>
</table>

**Abbreviations:** HepB = hepatitis B vaccine; anti-HBs = hepatitis B surface antigen antibody; HBsAg = hepatitis B surface antigen.

* If infant received testing for HBsAg and anti-HBs on different dates, the later test date was used.

† Age at testing could not be calculated because test dates were not reported.
<table>
<thead>
<tr>
<th>Serologic outcome</th>
<th>No.</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protected</strong></td>
<td>2,504</td>
<td>(93.3)</td>
</tr>
<tr>
<td>Anti-HBs-positive,† HBsAg-negative</td>
<td>2,504</td>
<td>(93.3)</td>
</tr>
<tr>
<td><strong>HBV-infected</strong></td>
<td>32</td>
<td>(1.2)</td>
</tr>
<tr>
<td>Anti-HBs-negative, HBsAg-positive</td>
<td>28</td>
<td>(1.0)</td>
</tr>
<tr>
<td>Anti-HBs-positive, HBsAg-positive</td>
<td>2</td>
<td>(&lt;0.1)</td>
</tr>
<tr>
<td>Anti-HBs,§ HBsAg-positive</td>
<td>2</td>
<td>(&lt;0.1)</td>
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<tr>
<td><strong>Susceptible</strong></td>
<td>87</td>
<td>(3.2)</td>
</tr>
<tr>
<td>Anti-HBs-negative, HBsAg-negative</td>
<td>87</td>
<td>(3.2)</td>
</tr>
<tr>
<td><strong>Indeterminate</strong></td>
<td>60</td>
<td>(2.3)</td>
</tr>
<tr>
<td>Anti-HBs-positive, HBsAg§</td>
<td>36</td>
<td>(1.3)</td>
</tr>
<tr>
<td>Anti-HBs-negative, HBsAg§</td>
<td>1</td>
<td>(&lt;0.1)</td>
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<tr>
<td>Anti-HBs, § HBsAg-negative</td>
<td>18</td>
<td>(0.7)</td>
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<tr>
<td>Anti-HBs, § HBsAg§</td>
<td>5</td>
<td>(0.2)</td>
</tr>
</tbody>
</table>

**Abbreviations:** PVST = postvaccination serologic testing; anti-HBs = hepatitis B surface antigen antibody; HBsAg = hepatitis B surface antigen.

* Infant PVST outcome was excluded if test date was not reported (n = 561).
† Defined as titer result ≥10 mIU/mL.
§ Serologic test result not reported.
Conclusions

- Timely completion of Hepatitis B series dose
- **Universal birth dose**: Hospitals and birthing centers, Honor role for all 583 hospitals
- **2nd and 3rd doses Medical Home**
- Post Vaccine Serological Testing
- **HBsAg** and **AntiHBs** for all infants born of HBsAG positive mothers at 9 months or 1 month after the last dose
Thank you!