



2012 Evaluation of Birthing Hospitals on Perinatal Hepatitis B Prevention Practices

Introduction

This report includes background on perinatal hepatitis B infection and prevention in the U.S. It also includes results of the 2012 Evaluation of Birthing Hospitals on Perinatal Hepatitis B Prevention Practices. This project was done by the Washington State Department of Health (DOH) to evaluate perinatal hepatitis B prevention policies and practices in birthing hospitals across the state.

Background on Hepatitis B

Hepatitis B virus (HBV) infection can cause serious long-term health issues including chronic liver disease, liver cancer, and death. A 2011 study (Kowdley et al., 2011) in *Hepatology* involving review of 256 disease prevalence surveys of emigrants, suggests the total prevalence of chronic HBV exceeds two million cases in the U.S.; twice the number previously reported. Over half of these were estimated to be foreign-born, most from Asia, the Pacific Islands, and Africa where HBV is highly endemic (Kowdley et al., 2011; Vijayadeva, et al., 2012). This study emphasizes hepatitis B as an important public health concern for the U.S. and that the need for a coordinated public health response is vital.

Babies are at highest risk of infection if the virus is passed from their infected mom during delivery or from infected household contacts. There are about 25,000 hepatitis B surface antigen (HBsAg) positive moms giving birth each year in the U.S. (Smith et al. 2012). Over 75 percent are women of Asian or Pacific Islander (API) descent (CDC, 2012). Infants born to HBsAg positive moms who become infected have a 90 percent risk of developing chronic HBV infection and have up to a 25 percent risk of dying prematurely from liver disease (CDC, 1991).

Washington State ranks fifth in the U.S. for API population. It's expected that, in the next 20 years, the API community will make up 10 percent of the total state population (http://advancingjustice-la.org/sites/default/files/A_Community_of_Contrasts_AANHPI_West_2015.pdf) with over 75 percent living in King, Pierce, and Snohomish Counties (Washington State Census 2010 data). This group, particularly foreign-born APIs, has an estimated hepatitis B prevalence of 8.9 percent, compared with 1.4 percent for U.S.-born APIs (Cohen, et al., 2008). This the scale of hepatitis B disease risk in our state and the importance of public health control efforts.

Over the last 20 years, national recommendations have evolved into a comprehensive strategy to eradicate HBV infection. Administration of the hepatitis B birth dose to all newborns before hospital discharge is recommended by several leading health organizations including the Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, and, most recently, the Institute of Medicine Committee on the Prevention and Control of Viral Hepatitis. Other recommendations include the administration of both

hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth for babies born to HBsAg positive moms or moms of unknown HBsAg status.

In addition, the Affordable Care Act supports prevention activities for viral hepatitis. Its focus is to expand access to preventative care to cover hepatitis B vaccine for many people, which will help prevent the spread of disease. Despite this support, data from the National Immunization Survey (NIS) reveal that national newborn hepatitis B birth dose rates have made, surprisingly, only small gains since implementation of the 2005 ACIP hepatitis B vaccination recommendations. The 2011 estimated coverage nationally between birth and 3 days of age is 68.6 percent (CDC, 2012).

Purpose and Goals

The purpose of this two-part assessment was to evaluate perinatal hepatitis B prevention (PHBP) policies and practices in birthing hospitals. This included identification of HBsAg positive pregnant women, hepatitis B vaccine birth dose administration, hospital policies, and appropriate care of infants born to moms with positive or unknown HBsAg status. A policy survey and medical records review were done. The findings from the project will help DOH assess accomplishment of programmatic goals and objectives, prioritize activities to prevent perinatal hepatitis B infections, and focus educational efforts to hospitals and healthcare providers to improve hepatitis B maternal screening and routine infant immunization.

This perinatal hepatitis B hospital evaluation project had two components: (1) a survey of policies and practices of all birthing hospitals in Washington State and (2) medical record reviews of maternal and newborn charts done in a sample of birthing hospitals. The Methodology, Results, and Discussion will be shown separately for each part. The Recommendations and Next Steps and Limitations and Strengths will be combined.

The 2012 Evaluation of Birthing Hospitals on Perinatal Hepatitis B Prevention Practices was a repeat of a similar project done in 2006 with some changes to data collection methods. Discussion of the results will include comparisons of the current project with findings from the 2006 evaluation.

Policy and Practices Survey

Methodology

All 66 hospitals in Washington State with recorded births in 2010 were eligible to receive the survey. The appropriate person to receive and complete the survey as well as their contact information was determined through phone calls to each hospital. In April 2012, a cover letter was sent to each hospital. It explained the evaluation goals and the project timelines. After that, a link to a Web-based survey (in Opinio) was emailed to each contact. In addition, email reminders and follow-up calls were made to birth center managers for all non-responders. If preferred by the hospital, surveys were done by phone (see appendix A). The survey included questions about whether the hospital had policies or standing orders for review of prenatal maternal HBsAg screening, maternal testing, and documentation and administration of the hepatitis B birth dose and HBIG. Other questions included continuous quality

improvement around hospital collection of hepatitis B birth dose rates and whether the hospital followed the National Quality Forum’s (NQF) hepatitis B birth dose measure.

Results

The following are responses from all birthing hospitals statewide. Hospital-specific results will be shared with each participating hospital and local health jurisdiction (LHJ) perinatal hepatitis B coordinator.

For the Web-based survey of Perinatal Hepatitis B Policies and Practices, 64 of 66 were completed for a response rate of 97 percent. Of the responding hospitals, 25 (39%) had fewer than 500 births in 2011, 22 (34%) had between 500 and 1999 births, and 17 (27%) had 2000 or more births. The range of births was 17 to 6333.

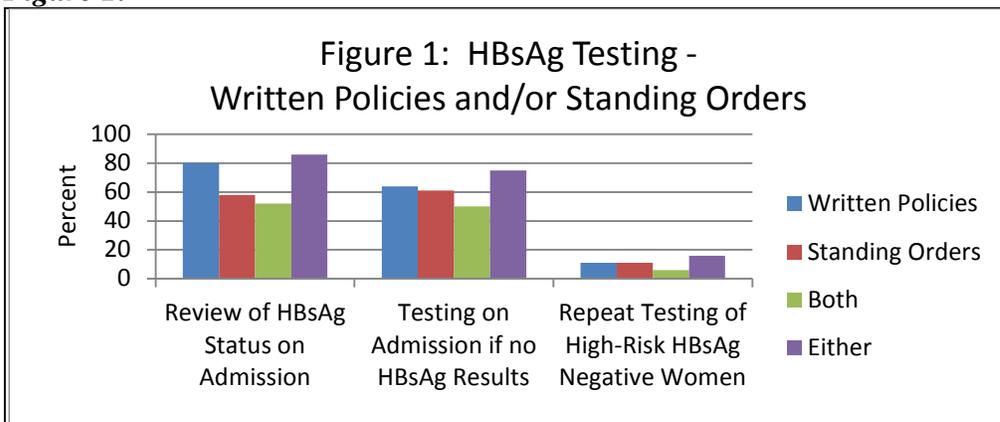
Respondents

The respondents included 13 nurses (20%), 19 nursing directors or clinical nurse managers (30%), 29 obstetrics directors or obstetric managers (45%), and 3 other professional categories (5%), including 1 midwife.

Review of HBsAg Status on Admission

- Of the birthing hospitals that completed the survey, 80 percent (51) reported a written policy to review prenatal HBsAg at the time of the moms’ admission to Labor and Delivery.
- Fifty-eight percent (37) had pre-printed standing orders to review the results at the time of admission for all pregnant women.
- Eighty-six percent (55) of birthing hospitals reported having either a written policy or standing orders for review of HBsAg test results at the time of the moms’ admission. Fifty-two percent (33) of hospitals reported that they had both written policies and standing orders (see Figure 1).

Figure 1:



Testing on Admission if no HBsAg Results

- Sixty-four percent (41) of birthing hospitals had a written policy for HBsAg testing as soon as possible after admission if no results were available.
- Of these hospitals, 61 percent (39) had pre-printed standing orders for this testing as soon as possible after admission when no test results were available.
- Seventy-five percent (48) of hospitals reported having either a written policy or standing orders for HBsAg testing on admission if no results were available.
- Fifty percent (32) of the birthing hospitals had both written policies and pre-printed standing orders for testing on admission of moms for whom HBsAg results were not available (see Figure 1).
- ***Thirty-nine percent (25) of birthing hospitals reported having both written policies and standing orders for both review of HBsAg status on admission and for testing on admission if no HBsAg results were documented.***

Repeat Testing of High-Risk HBsAg-negative Women

- Eleven percent (7) of hospitals reported having a written policy for repeat testing of HBsAg-negative women who have had clinical hepatitis or who are at risk for HBV infection during pregnancy. This group includes those who have had more than one sexual partner in the previous six months, evaluation or treatment for a sexually transmitted disease (STD), recent or current injection drug use, or who have an HBsAg-positive sexual partner.
- Eleven percent (7) reported having pre-printed standing orders for repeat testing of HBsAg-negative moms at high risk for hepatitis B infection during pregnancy.
- Sixteen percent (10) of birthing hospitals reported having either a written policy or a standing order for repeat testing of HBsAg-negative women at risk for HBV infection during pregnancy.
- Six percent (4) reported having both a written policy and a standing order for repeat testing of high-risk HBsAg-negative women (see Figure 1).

HBIG Administration

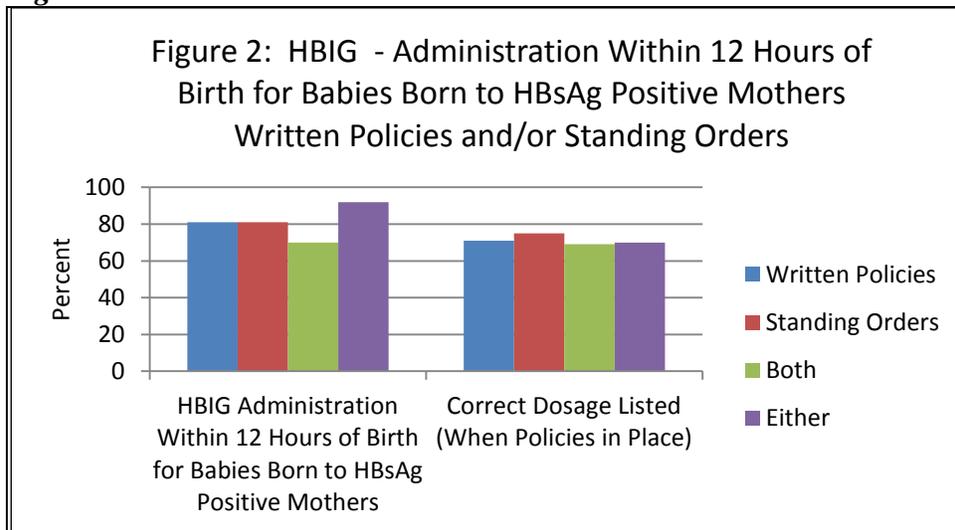
- Eighty-one percent (52) of birthing hospitals reported having a written policy for HBIG administration within twelve hours of birth for all infants born to HBsAg-positive moms.
- Eighty-one percent (52) reported having a standing order for HBIG administration to these newborns at high risk for transmission of hepatitis B.
- Ninety-two percent (59) of birthing hospitals reported having either a written policy or a standing order for HBIG within twelve hours of birth for all infants born to HBsAg-positive moms.
- Seventy percent (45) reported having both a written policy and a standing order for HBIG administration within this time period after birth for babies born to HBsAg-positive moms (see Figure 2).

HBIG Dosage

- Seventy-one percent (37) of hospitals with a written policy for HBIG administration to high-risk newborns listed the correct dosages: 0.5 mL, 5, or 10 mcg depending on the formulation of the specific brand used.
- Seventy-five percent (39) of hospitals with pre-printed standing orders for HBIG administration to babies born to HBsAg-positive moms listed the correct dosages for HBIG administration.
- Seventy percent of hospitals with either a written policy or a standing order listed the correct HBIG dosages.

- Of the hospitals that reported having both a written policy and a standing order, 69 percent (31) listed the correct HBIG dosage (see Figure 2).

Figure 2:



Hepatitis B Vaccination

For newborns of HBsAg-positive moms:

- Seventy-eight percent (50) of birthing hospitals reported having written policies for hepatitis B vaccine administration within twelve hours of birth for babies born to HBsAg-positive moms.
- Seventy-seven percent (49) of these hospitals had pre-printed standing orders for hepatitis B vaccination within twelve hours of birth for babies born to HBsAg-positive moms.
- Eighty-eight percent (56) of birthing hospitals reported having either written policies or standing orders for hepatitis B vaccination within twelve hours for babies born to moms with positive HBsAg status.
- Sixty-six percent (42) of hospitals had both written policies and standing orders for this vaccine administration and a time schedule for newborns of HBsAg-positive moms (see Figure 3).

For babies born to moms of unknown HBsAg status:

- Seventy-three percent (47) of the hospitals had written policies for hepatitis B vaccine within twelve hours of birth for babies born to moms of unknown HBsAg status.
- Sixty-nine percent (44) had standing orders for vaccination within twelve hours for babies of moms of unknown status.
- Eighty percent (51) of hospitals had either a written policy or standing orders for hepatitis B vaccination within twelve hours for babies born to moms of unknown HBsAg status.
- Sixty-three percent (40) had both written policies and standing orders for this vaccine administration for these at-risk newborns (see Figure 3).

For all newborns prior to hospital discharge:

- Eighty-one percent (52) of birthing hospitals had written policies for the administration of hepatitis B vaccine to all newborns before discharge from the hospital.
- Eighty-nine percent (57) of hospitals had standing orders for hepatitis B vaccine for all births.

- Ninety-one percent (58) of birthing hospitals reported having either a written policy or standing orders for hepatitis B vaccination for all newborns prior to hospital discharge.
- Eighty percent (51) had both written policies and pre-printed standing orders for routine vaccination with the hepatitis B birth dose (see Figure 3).

Hepatitis B vaccine dosage:

- Of the birthing hospitals that reported having written policies or standing orders for vaccine administration, eighty-four percent listed the correct dosage of hepatitis B vaccine. However, the dosage information was collected only on the questions for moms of unknown HBsAg status (see Figure 3).
- ***Sixty-three percent (40) of birthing hospitals reported having both written policies and standing orders for both HBIG and hepatitis B vaccine administration within twelve hours to babies born to HBsAg-positive moms.*** (This information was requested by the Centers for Disease Control and Prevention (CDC) for its Annual Assessment of Progress Toward Goals to Prevent Perinatal HBV Transmission – 2011-2010 Birth Cohorts.)

Figure 3:

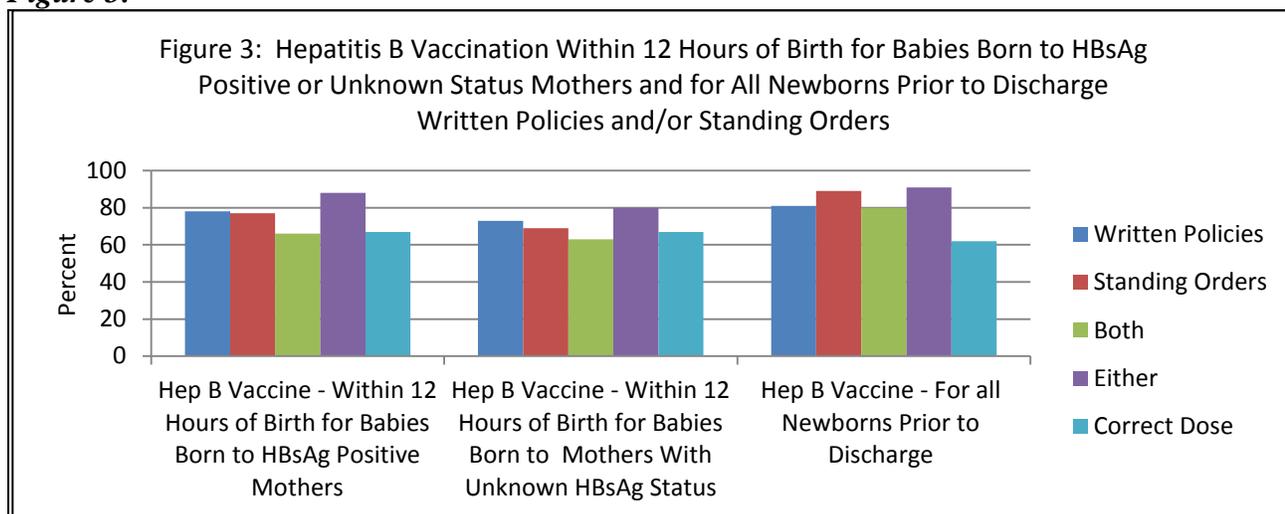


Chart Documentation and Perinatal Hepatitis B Data Collection:

- Of the surveyed hospitals, 64 percent (41) reported having a written policy for documentation of maternal HBsAg test results in the infant medical record.
- Thirty-three percent (21) of hospitals reported collecting data on hepatitis B birth dose coverage.
- Twenty-seven percent of respondents did not know if these data were collected by their hospital.

Knowledge of NQF Hepatitis B Birth Dose Measure on Hepatitis B Prevention

- Fifty-two percent (33) of respondents said they did not know if their hospital uses the NQF hepatitis B birth dose measure on hepatitis B prevention.
- Twenty-five percent (16) answered that their hospital did use the NQF hepatitis birth dose measure.
- Twenty-three percent (15) responded that their hospital did not use this measure.

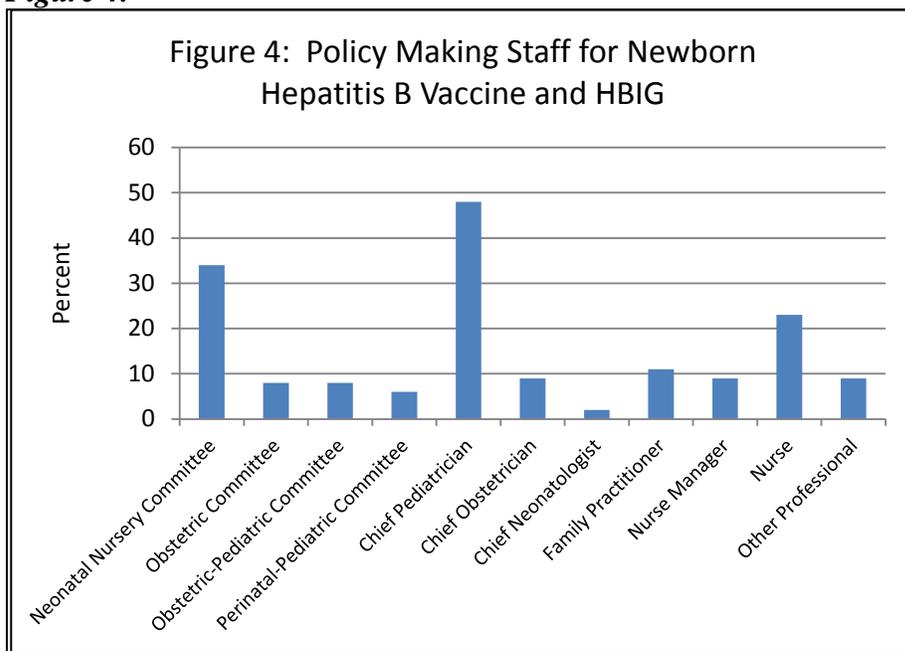
Washington State’s Universal Childhood Vaccine Program

- Fifty-two percent (33) of hospitals reported receiving hepatitis B vaccine at no cost for the birth dose to newborns through Washington State’s Universal Childhood Vaccine Program.
- Thirty-four percent (22) reported that they did not know.
- Fourteen percent (9) of hospitals reported they did not receive no-cost vaccine for the birth dose from this source.

Staff Responsible for Hepatitis B Vaccine and HBIG Policy for Newborns

Since respondents could give more than one answer, the totals do not add up to 100 percent (see Figure 4).

Figure 4:



Discussion

Of the birthing hospitals contacted for the Survey of Perinatal Hepatitis B Policies and Practices, 64 of the 66 (97%) responded in 2012 compared with 100 percent of the 69 hospitals in 2006. These response rates were excellent and contribute to the results being generalizable to the total group of birthing hospitals within Washington State.

On both the 2012 and 2006 survey, we asked about the presence of hospital written policies and standing orders. However, for both surveys, there are concerns about how well the respondents’ understand the difference between the two despite our attempt to clarify it through the addition of the words “pre-printed” to standing orders. It’s for this reason that we believe the estimates of having either a written policy or a standing order is a more accurate reflection of the hospitals’ understanding of the need to implement these recommendations.

Overall there was an increase from 2006 in the percentage of hospitals that reported either written policies or standing orders for most of the recommended perinatal hepatitis B “Best Practices” or “Standards of Care.”

This was true for the review of maternal HBsAg status at the time of hospital admission for delivery and testing as soon as possible after admission for mom whose test results were not available. Nevertheless, there was a decrease in the reported rate of repeat HBsAg testing for negative women at high risk of HBV infection during pregnancy. Only 11 percent reported having written policies for this targeted repeat testing in 2012 compared with 55 percent in 2006.

In 2006 there was an increase in the percentage of hospitals having either written policies or standing orders for the administration of HBIG within 12 hours of birth for infants born to HBsAg-positive moms (92%) from 74 percent for written policies and 70 percent for standing orders. On the other hand, there was a 71 percent decrease for reporting the correct dose of HBIG by hospitals with written policies and a 75 percent decrease by hospitals with standing orders from 90 percent and 88 percent respectively in the same time interval. As in 2006, the 2012 survey did not include questions about HBIG administration to newborns of moms of unknown HBsAg status, although this is the recommendation from the CDC.

In 2012, hospitals reported increased percentages of having written policies or standing orders for hepatitis B vaccination within 12 hours of birth for newborns of HBsAg-positive (88%) or HBsAg-unknown (80%) moms and for all newborns before hospital discharge (91%). As with dosages for HBIG, a smaller percentage reported the correct vaccine dose in 2012 than in 2006, although the question of dosage of vaccine was asked only for moms of unknown HBsAg status. It should be noted that maternal status did not yield any major differences for HBIG doses and, most likely, would not either for vaccine doses.

In terms of hospitals reporting having a written policy for documentation of maternal HBsAg test results in the infant chart, there was an increase from 59 percent in 2006 to 64 percent 2012. Interestingly, less than one third of hospitals reported collecting data on hepatitis B birth vaccination coverage and almost one third did not know whether these data were collected by their hospital. These last two questions were not included in the 2006 survey.

Another new question was if the hospital used the NQF hepatitis B birth dose measure on hepatitis B prevention. Only 25 percent of respondents answered “Yes” while over half answered that they did not know. This question was included to see if there was a need for hospital-focused education on this quality assurance measure that Hospital Accreditation agencies are starting to use.

The survey results also showed a drop to slightly over half of respondents reporting that their hospital received hepatitis B birth dose vaccine at no cost through the Washington State Universal Childhood Vaccine Program, while 34 percent reported that they did not know and 14 percent reported that they did not receive vaccine from this source. According to the most recent records, on the other hand, 68 percent of birthing hospitals are currently enrolled as Vaccines for Children (VFC) providers and should already be receiving vaccine from this source. The specific person answering the survey, however, may have been unaware of this, which resulted in the lower number of positive responses.

Overall, the results of the Policy and Practices Survey showed an improvement in the presence of written policies and standing orders in keeping with CDC recommendations for perinatal hepatitis B prevention “Best Practices.” Areas that need further attention, educational efforts, and materials include:

- Repeat testing of high-risk pregnant women.
- HBIG administration to infants born to moms of unknown HBsAg status.
- Appropriate HBIG and hepatitis B vaccine dosages.
- Availability of no-cost vaccine for the birth dose of hepatitis B vaccine for all babies born in Washington State.

Medical Record abstraction

Methodology

The second activity included reviewing hospital medical records for 30 clusters of hospitals with more than 300 births in 2011. Military hospitals were included in the sampling frame. There were 47 eligible hospitals. The sampling methodology was probability proportional to size (PPS) cluster sampling.

Birth files from the Center for Health Statistics of all 81,437 children born in Washington State from January 1 through September 30, 2011 were used as the sampling frame. Thirty clusters of twenty-five births each were selected from twenty-six hospitals (750 mother-baby pairs or 1500 records). One hospital declined to participate, which resulted in a final sample size of 725 births. Four hospitals had two clusters each (50 mother-baby pairs).

A standardized electronic data entry form developed in Access was loaded onto laptops to record infant and maternal data. These forms did not include any patient identifiers but included a hospital identification code. Access to the forms, and to the specific laptops, was obtained by use of passwords unique to each of the four study staff assigned to abstract the medical records.

Hospital medical records were reviewed June through October 2012. Onsite reviews were done in 11 of the hospitals. Eleven hospitals made records available through a secure online server that study staff downloaded. Two hospitals mailed a hard copy of the medical records, and one mailed a CD of the medical records. Electronic files were stored in a secure folder accessible only to designated study staff. Hard copy files were stored in locked file cabinets in a secure area. These files were available only to designated study staff.

Information abstracted from both the maternal and infant charts included demographics, prenatal and intrapartum testing, test results and documentation of these results, type of provider, infant receipt of hepatitis B vaccine and/or HBIG, and the use of standing orders.

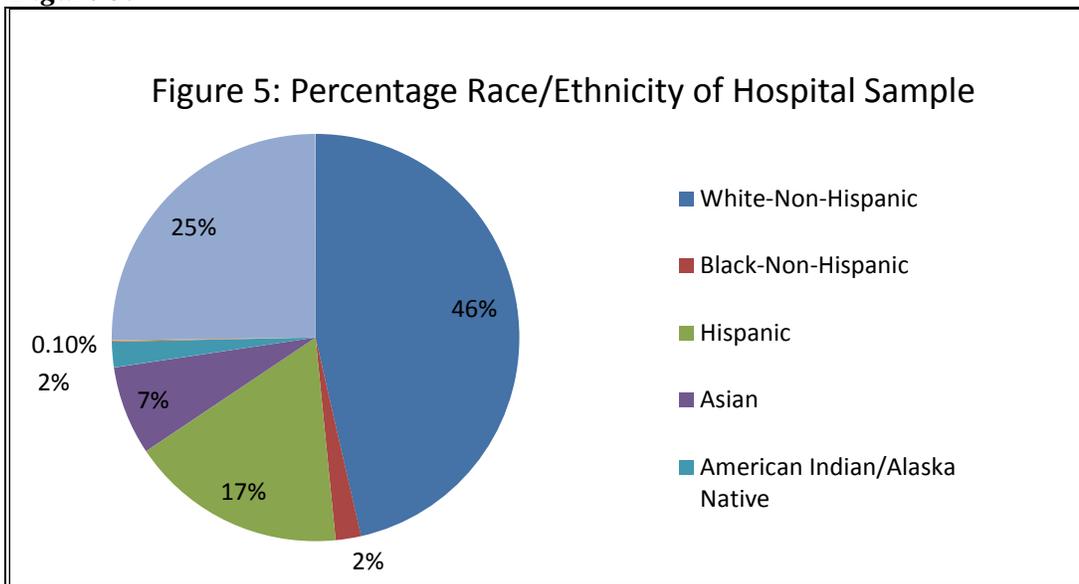
Results

The following are findings from the medical record abstraction of the 1450 mother-baby charts (725 pairs) of 2011 births from the 25 participating hospitals selected by the PPS cluster sampling methodology.

Race/Ethnicity

- Of the 725 births included in the medical record abstraction, 46 percent (335) were White, Non-Hispanic.
- Two percent (18) of the hospital sample were Black, Non-Hispanic.
- Seventeen percent (123) of the hospital sample were Hispanic.
- Less than 10 percent of the sample were Asian (54), American Indian/Alaska Native (15), or Native Hawaiian/Other Pacific Islander (1), which are considered at higher risk for hepatitis B disease.
- Twenty-five percent (179) of the hospital sample were listed as Other or did not have a race or ethnicity listed (see Figure 5).

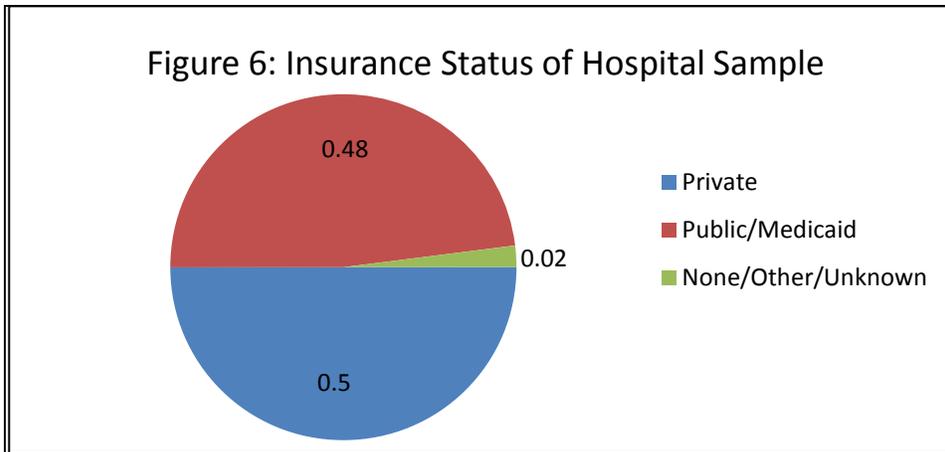
Figure 5:



Insurance Status

- Of the hospital sample, 50 percent (363) were listed as having private medical insurance.
- Forty-eight percent (347) of the sample were listed as having public insurance or Medicaid.
- Two percent (15) of the hospital sample had no medical insurance recorded in the medical record (see Figure 6).

Figure 6:



Type of Obstetrical Provider

The type of obstetrical provider is listed below. Data from one hospital is missing from the analysis since the information was not collected.

- Obstetricians—71 percent (481)
- Family practice physicians—11 percent (75)
- Midwives—9 percent (59)
- Nine percent (15) of the hospital sample did not have a specific type of obstetrical provider listed (see Figure 7).

Figure 7:

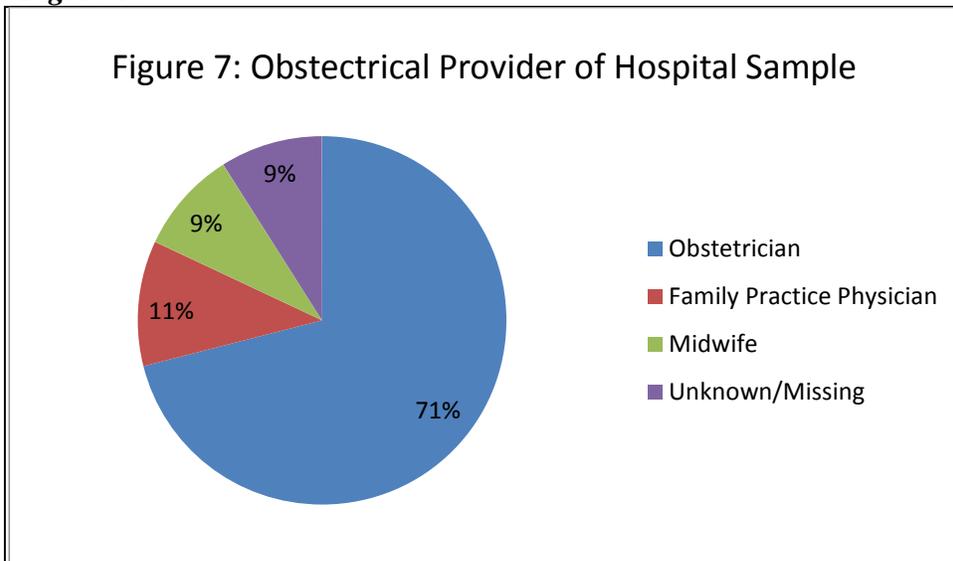


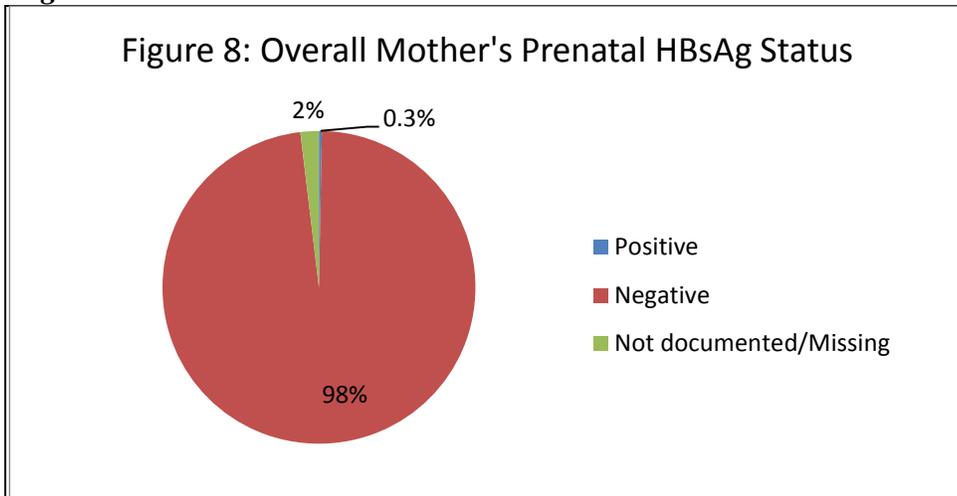
Table 1:

HBsAg Testing	Percent	n
HBsAg Testing Prior to Admission	94%	681

Documentation of date (of those with HBsAg testing prior to admission)	55%	374
Results of HBsAg of those with testing prior to admission:		
Positive	0.3%	2*
Negative	98%	668
Not documented/Missing	2%	12
HBsAg Testing After Admission	3%	22
Results of HBsAg of those with testing after admission:		
Positive	5%	1
Negative	95%	21
Not documented/Missing	--	0
Maternal HBsAg Result in Baby's Chart	91%	658
Mom's HBsAg status of those with results in baby's chart		
Positive	0.3%	2
Negative	99.7%	656
Not documented/Missing	--	0
Overall Mom's Prenatal HBsAg Status		
Positive	0.3%	2
Negative	97.8%	709
Not documented/Missing	1.9%	14

(*Note: one of these mothers was not listed as having been tested prior to admission, but the result was documented.)

Figure 8:



Documentation of Prenatal HBsAg Status

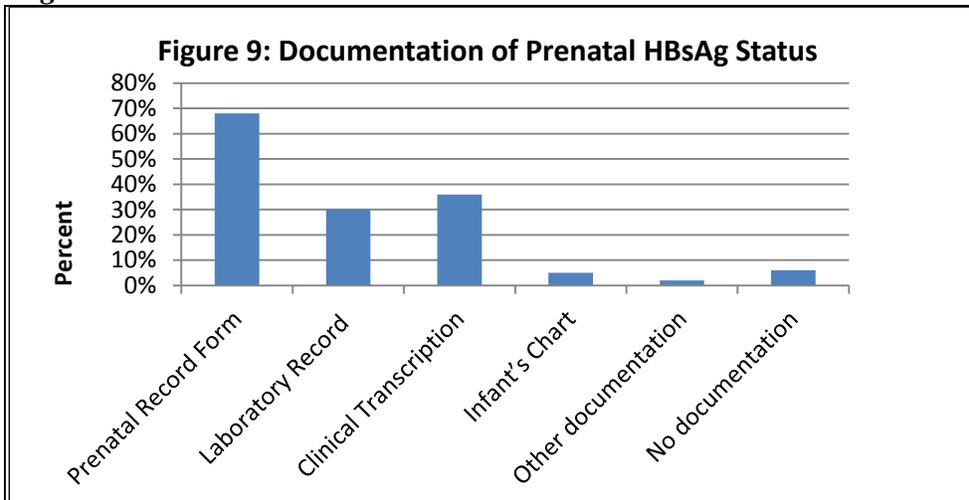
The vast majority, 94 percent of the hospital sample had some documentation of the mom's prenatal HBsAg status. Since documentation was often found in more than one place in either or both the mom's and infant's medical record, the totals do not add up to 100 percent (see Table 3 and Figure 9).

Table 2:

Documentation of Prenatal HBsAg Status	Percent	Number
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		(N)
Prenatal Record Form	68%	493
Lab Record	30%	217
Clinical Transcription	36%	263
Infant's Chart (when not in mom's chart)	5%	33
Other documentation	2%	11
No documentation	6%	46

Figure 9:

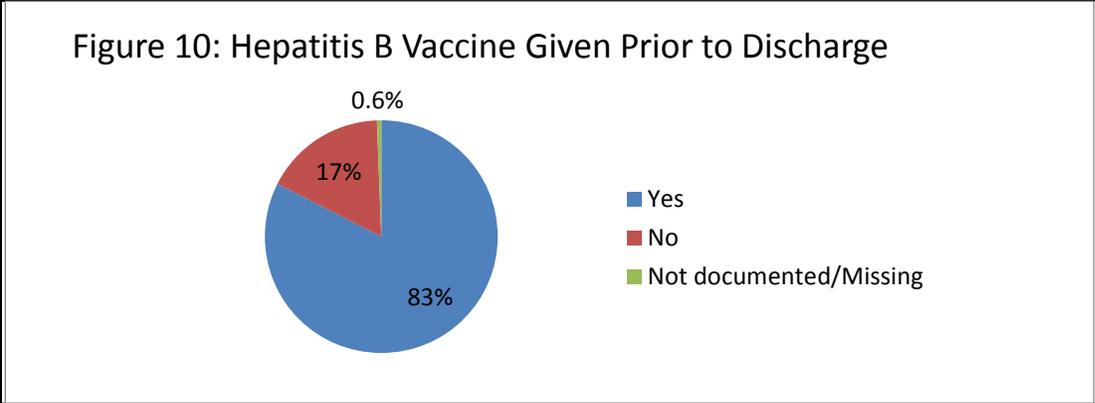


The two babies born to HBsAg-positive moms both received HBIG and hepatitis B vaccine within twelve hours of birth.

Hepatitis B Vaccine Given to All Babies Prior to Discharge

- Of newborns in the hospital sample, 83 percent (601) received hepatitis B vaccine prior to discharge.
- Seventeen percent (120) of newborns did not receive hepatitis B vaccine prior to discharge.
- Information was missing for 0.6 percent (4) of newborns in the hospital sample of receipt of hepatitis B vaccine prior to discharge (see Figure 10).

Figure 10:



Hepatitis B Vaccine Given Due to Standing Orders or Physician Order

For the 601 infants who received hepatitis B vaccine prior to hospital discharge:

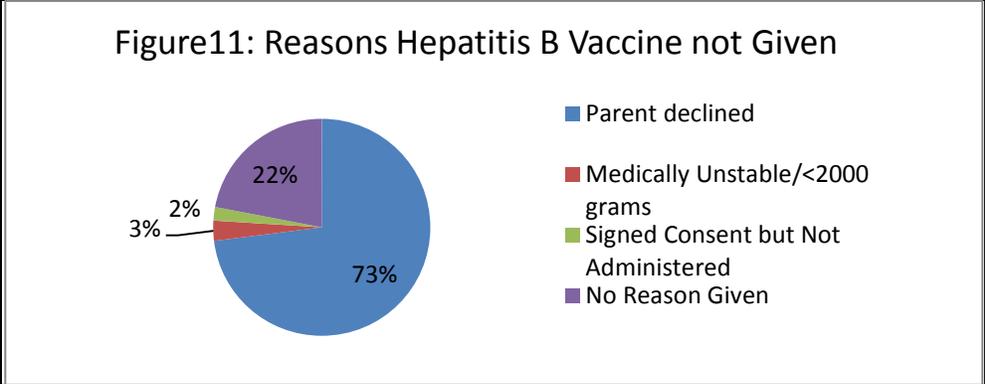
- Ninety-two percent (551) received the vaccine due to pre-printed standing orders.
- 0.8% (5) newborns received the hepatitis B vaccine due to a specific physician order

Reasons Vaccine Not Given

For the 124 newborns who were listed in the medical record as either not having received the hepatitis B vaccine prior to discharge or for whom there was no documentation of whether or not they had received it:

- Seventy-three percent (91) had the reason listed that the parent declined the vaccine.
- Three percent (4) were listed as being medically unstable or weighing less than 2000 grams at birth.
- Two percent (2) of the newborn charts had signed consents for the administration of the hepatitis B vaccine but no documentation that the vaccine was given.
- Twenty-two percent (27) of infant medical records that had no documentation of having received the hepatitis B vaccine prior to discharge had no reason included for why it was not given (see Figure 11).

Figure 11:



Discussion

Medical record abstraction of both mother and infant charts was completed for all 725 mother-baby pairs selected from births from January through September 2011 in Washington State.

As with the 2006 project, 17 percent of the sampled births were Hispanic, while a slightly smaller percentage were White, Non-Hispanic (46% for 2012 vs. 54% for 2006). In the more recent project, 25 percent of the sample was listed as Other or did not have a race or ethnicity listed compared with 17 percent in the earlier project. The percentages of Asian, Native Hawaiian, or Other Pacific Islander or American Indian or Alaskan Native remained about the same as less than 10 percent, as did Black, Non-Hispanics.

As was the case in the earlier project, insurance status was almost evenly divided between private and public with only 2 percent missing. Since this variable was taken from the medical record, it's considered more valid than if obtained from self-report or patient survey.

The obstetrical providers for moms included in the sample were mostly (71%) obstetricians with the remainder almost evenly divided between family practice physicians (11%) and midwives (9%). Nine percent had no provider listed. It must be noted, however, that many patients had different providers listed for prenatal care, admission, and delivery. There may have been an abstractor bias to list the delivery specialty, which was more likely to be obstetrics.

Ninety-four percent of moms had documented HBsAg testing prior to admission, although one had a positive result listed without documentation that the testing had occurred. Three percent of moms had HBsAg testing after admission for delivery and, overall, 91 percent had maternal HBsAg status recorded in the newborn's medical record. All sources combined yielded the mom's prenatal HBsAg status as 0.3 percent positive, 98 percent negative, and almost 2 percent had no results available.

One of the two moms with positive HBsAg status was Asian and the other had no race or ethnicity noted in the medical record. Both of the babies born to positive moms received both HBIG and hepatitis B vaccine within 12 hours of birth, and both birthing hospitals had pre-printed standing orders for administration of both HBIG and the vaccine within this time limit.

Almost 83 percent of the total sample of newborns received hepatitis B vaccine in the hospital as per CDC recommendations, 17 percent (120) had either notation that they had not been vaccinated prior to discharge or there was no documentation of whether or not the vaccine had been administered. Parents or guardians declined hepatitis B vaccine for most (73%) of the infants who did not receive the vaccine. Only 3 percent who did not receive the vaccine were noted as being medically unstable or weighing less than 2000 grams at birth.

In summary, the aggregate findings showed a high rate of compliance with CDC recommendations for perinatal hepatitis B prevention including appropriate HBsAg testing of pregnant women and both HBIG and hepatitis B vaccination prophylaxis within 12 hours of birth for infants born to HBsAg-positive moms. It was also evident that standing orders and the presence of written hospital policies are effective in the assurance of compliance with recommended practices.

However, there were also some areas of notably poor or decreased compliance that will need to be addressed through targeted trainings. These include knowledge of the correct dosages for both HBIG and hepatitis B vaccine, appropriate prophylaxis for infants born to moms of unknown HBsAg status, repeat testing of pregnant women at high risk for developing hepatitis B infection, and knowledge of methods to increase and ensure implementation of CDC recommendations. In addition, through the medical record abstraction process, we became aware that not all birthing hospitals routinely administer HBIG to babies born to moms of unknown HBsAg status and have informally heard that this is due to cost. This warrants special attention since it's considered an important recommendation for prevention of perinatal hepatitis B.

Further concerns include the high proportion of guardian and parental refusal of administration of the hepatitis B birth dose prior to hospital discharge. This not only delays the initiation of the three-dose series but increases the possibility of the child not being vaccinated at all.

Discussion of Methods used for the Medical Record Abstraction

In earlier projects, medical record abstraction was done mainly through onsite abstraction of hard copy charts with a few hospitals using microfiche records. The 2012 project did not have resources to send abstractors to all the hospitals and, consequently, a mix of methods were used to get access to the charts.

Onsite reviews were done at 11 hospitals. Eleven hospitals uploaded electronic copies of photocopied portions of the charts via a secure server, two hospitals sent hard copies of photocopied portions of the charts, one hospital sent a CD of photocopied portions of the charts, and one hospital allowed access to their electronic server. All but one of the onsite record reviews used electronic medical records (EMRs) while one still used paper charts.

The mix of methods provided several challenges and limitations. While it appeared that the medical information available onsite and through direct server access was more complete, there were significant areas where the newer EMR systems lacked the completeness of the older hard copy charts. One example of this is in the use of combined electronic lab report forms that in very few cases included copies of the original lab forms. Thus, lab information may have been missed or changed in transcription from the original slips. There were also gaps in integrating standing orders into the EMR, even in hospitals where they were definitely in place. Furthermore, the complexity of EMRs and differences between systems made locating some of the needed information difficult. These challenges were magnified when the records were transmitted electronically to our offices since it was difficult, and often impossible, to determine if lack of detailed information was truly missing or simply not transferred. There were also some technical glitches in the electronic transfers which may have resulted in undetected errors.

Despite these limitations and challenges, it's recognized and acknowledged that EMRs are becoming the standard way of maintaining and sharing hospital medical record information. It's no longer feasible to rely on in-person data collection due to the lack of hospital terminals for accessing these data, room for record reviews, and the resource burden on the hospital staff to try to provide the assistance for this activity. It also requires more staff time and money to travel in addition to the time needed to get the required information. As a consequence, an additional strength of this project is that it successfully incorporated this newer method of abstraction. With the exception of one identified systematic error in

the lack of notation of type of maternal obstetrical provider from one hospital, which was handled by the decision to not include those data from the analysis, most of the potential errors or data omissions appeared to be random.

Overall Recommendations and Next Steps

The completed report of this project will be shared with all birthing hospitals in Washington State as well as with the LHJs. In addition, each hospital will get a report of their individual responses to the survey. Hospitals should review their responses in light of the recommended best practices for the presence of standing orders, written policies, prenatal screening and documentation of screening results, prophylaxis of high-risk infants, and universal newborn vaccination. These, as well as some additional recommendations to hospitals, are listed below:

Recommendations to Hospitals:

- Adopt and enhance a hepatitis B birth dose written policy, protocol, and standing order to offer hepatitis B vaccine to all infants before discharge. Provide training and education to staff addressing policy. Sample policies are available from DOH and the Immunization Action Coalition (IAC) website <http://www.immunize.org/catg.d/p2130.pdf>
- Adopt a hepatitis B birth dose and prophylaxis with HBIG policy for infants whose moms are HBsAg-positive or whose status is unknown.
- Assess risk of all pregnant women upon admission with repeat testing of high-risk women and assure documentation of the mom's hepatitis B status in both the mom and infant record. This may include programming EMR fields that assists with alerts, prompts, or call outs.
- Create a process or a two-way communication between the hospital and LHJ for all HBsAg-positive deliveries. Report all HBsAg-positive pregnant women and their newborn to the LHJ to enroll newborns into the case management programs and refer mom, infant and susceptible household contacts for follow-up care.
- Enroll in Washington State's Universal Childhood Vaccine Program, which provides hepatitis B vaccine at no charge to birthing hospitals.

In addition, specific areas that showed poor or decreased adherence to standard guidelines warrant special efforts:

- Clarification about the dosages for both HBIG and hepatitis B vaccine will need to be disseminated to all the hospitals and reviewed with staff to ensure that all newborns get effective prophylaxis.
- Lack of universally consistent policies and practices for appropriate prophylaxis of infants born to moms of unknown HBsAg status shows the need for targeted educational efforts. These efforts should emphasize the importance of both maternal testing upon hospital admission if screening results are not available, as well as the need for administration of HBIG and vaccine within 12 hours of birth to all infants born to moms of unknown status.

- The development and distribution of educational materials and trainings for hospitals regarding the importance of repeat testing of HBsAg-negative pregnant women at high risk for developing hepatitis B infection could also contribute to prevention efforts.
- Lack of consistency with location of HBsAg lab results in the medical chart for both mom and baby.
- Inconsistent recording of maternal HBsAg test results on both labor and delivery record and infant's medical chart.
- Very few copies of original lab reports were found on prenatal care records included in medical charts. Often, lab reports for HBsAg-positive women were found on prenatal care records included in medical charts and frequently these results may have been handwritten or transcribed. A copy of the original lab report showing the pregnant woman's status should be provided to the delivery hospital.

Another important concern is the high proportion of guardian and parental refusal of administration of the hepatitis B birth dose before hospital discharge. This not only delays the initiation of the three-dose series, but increases the possibility of the child not being vaccinated at all. Staff training to nurses and medical staff is imperative. Feedback and recommendations from the 2012 perinatal hepatitis B hospital review will be shared with LHJs. Additionally, outreach, using the IAC birth dose campaign materials will be shared with professional organizations, academic institutions, insurance carriers, labs, family planning organizations, and state agencies that work with maternal and child health issues. Campaign materials will give the most up-to-date education and reinforce their role as valuable in responding to this important public health challenge.

Limitations

As with all surveys, one limitation present for the Policy and Practices Survey is response bias in which respondents may tend to give answers that they perceive to be "correct" or socially acceptable. Since the survey respondents were identified, this could have played a part in their answers. However, the survey was similar to a survey done in 2006 and, while many of the overall responses were similar, there were also declines in the reporting of some selected best practices leading us to believe that response bias was not a major influence in the findings. In addition, there may still be some confusion between a "written policy" and a "standing order" although the confusion was less in 2012 than in 2006 due to adding the words "pre-printed" in describing a standing order in the more recent survey.

Strengths

- This was a statewide project involving all birthing hospitals in the Policy and Practices Survey. The sample chosen for the medical record abstraction was from all hospitals with 300 or more live births in 2011. The sampling methods were chosen to provide statewide estimates.
- There was a 97 percent response rate to the policy survey, which contributes to confidence that the results are generalizable to the total population of birthing hospitals in Washington State.
- Data entry quality for the survey improved over the 2006 survey since the majority of respondents completed the Web-based survey which required no additional data entry.

- With the exception of one hospital with a sample of 25 mother-baby pairs, all hospitals selected for the abstraction by the cluster methodology participated and all maternal and infant charts were available for review. This resulted in a response rate of 97 percent.

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