Evaluation of Adherence to Guidelines to Prevent Perinatal Infections in Oregon

Oregon Active Bacterial Core Surveillance (ABCs)
Office of Disease Prevention & Epidemiology
Oregon Department of Human Services
July 2009

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Background

Adapted from the Protocol for the Evaluation of Adherence to the 2002 Revised Guidelines for the Prevention of Perinatal GBS Disease (Unpublished), by Christina Phares, PhD, Stephanie Schrag, DPhil, Elizabeth Zell, MStat, Katie Arnold, MD, Allen Craig, MD, Ruth Lynfield, MD, Janet Mohle-Boetani, MD, Aaron Roome, PhD, and Ann Thomas, MD, MPH, for the Active Bacterial Core Surveillance Team.

The vertical transmission of infections from mother to child is a major cause of newborn morbidity and mortality. Over the past few decades, interventions to prevent the transmission of certain infections during pregnancy and labor and delivery, such as Group B Streptococcus (GBS), Hepatitis B virus (HBV), human immunodeficiency virus (HIV), syphilis, *N. gonorrheae*, *C. trachomatis*, and rubella have been implemented to reduce the burden of these diseases among neonates. For instance, the CDC joined with the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP) in 1996 to issue guidelines for the prevention of perinatal GBS disease through risk-based prenatal screening for GBS colonization and providing antimicrobial prophylaxis to GBS-positive women intrapartum [1-3]; universal prenatal screening for *C. trachomatis*, *N. gonnorheae*, syphilis was recommended in 1989, for HBV in 1991, and for rubella most recently in 1998; and voluntary HIV testing for pregnant women was recommended in 1995 [4-7].

In Oregon, as nationwide, the effect of these guidelines has generally been observed through a combination of passive and active communicable disease surveillance programs, which track the occurrence of these diseases in infants. For instance, coinciding with the first guidelines in 1996, early-onset GBS disease declined 70%, from 1.5 per 1,000 live births in 1993 to 0.5 per 1,000 live births in 1999 [8-9]. ACIP recommendations and work by the Oregon Immunization Program have led to a significant increase in HBV birth dose coverage by Oregon hospitals; from 32% of infants vaccinated in 2004 to 65% vaccinated to date in 2009 (unpublished Oregon data). In spite of comprehensive follow up efforts to ensure that infants born to HBsAg positive mothers receive HBIG and the HBV vaccine series, Oregon experiences 1-2 cases of perinatal hepatitis B annually. Additionally, an average of 5-6 congenital rubella syndrome cases have occurred annually, nationwide, for the past two decades, with only two cases reported in 2001 and no cases reported in 2004 [10].

Due to design and rarity of occurrence of each of these diseases, however, surveillance programs are not sufficient to capture the uptake of or adherence to the respective prevention guidelines in practice. To that end, specific evaluations are necessary. For instance, in 2002, the Oregon ABCs program – along with seven other sites, nationally – participated in a survey

of prenatal screening practices among live births occurring in 1998-1999 to gauge baseline compliance with stated recommendations for the above listed perinatal infections [11]. Since that time, however, revised guidelines endorsing universal screening of pregnant women for GBS carriage and updated guidance for use of intrapartum antibiotic prophylaxis have been issued [12]. An evaluation of adherence to these guidelines had not previously been performed and the extent to which prenatal screening practices have changed remains unknown.

This report details the results of a follow-up evaluation survey of prenatal screening and treatment practices for GBS, HBV, HIV, rubella, syphilis, *C. trachomatis*, gonococcus, and bacterial vaginosis (BV), as well as adherence to recommendations for treatment or prophylaxis against the diseases caused by these pathogens, among live births occurring in Oregon in 2003-2004. Such detailed knowledge of actual prevention practices will help to identify barriers to adherence and detect missed opportunities for prevention, which will in turn help to formulate strategies for increasing uptake of the guidelines.

Methods

This evaluation was conducted in the 10 states participating in the population-based Active Bacterial Core surveillance (ABCs) system for invasive GBS disease, including Oregon, and in a manner similar to an evaluation of adherence to guidelines to prevent perinatal GBS infections among births occurring in 1998-1999. [11,13] Briefly, maternal labor and delivery records for all births occurring in 2003-2004 resulting in early- or late-onset infant GBS disease in the Portland Tri-County (Clackamas, Multnomah, and Washington) Metropolitan area and a random sample of all Tri-County live births occurring during the same time period, stratified by hospital of delivery and year of birth, were eligible for inclusion. Within each stratum, birth records were selected by proportional allocation. Women who did not have labor and delivery charts were excluded from the evaluation.

For each birth record selected, the entire maternal hospital record was requested. Data was collected primarily from the labor and delivery record; for women presenting to the delivery hospital for premature labor not progressing to delivery, additional data were collected from the hospital record. Additional variables were collected from the vital records department. Data elements captured include maternal characteristics (age, race, ethnicity, receipt of Medicaid assistance status, and use of illegal drugs), antenatal indicators of perinatal infection prevention (i.e. adequacy of prenatal care and screening practices and results of screening for perinatal infections), characteristics of labor and delivery that may influence transmission of infections (gestational age at delivery, prolonged rupture of membranes, and indicators of maternal infection), and implementation of interventions to prevent infections in the infant (i.e. administration of intrapartum antibiotic prophylaxis [IAP] and hepatitis B vaccine).

Unless otherwise indicated, values were obtained using weighted analyses to account for the unequal probability of record selection. Analyses were conducted using SAS SURVEYFREQ and SURVEYLOGISTIC procedures (SAS Institute; Cary, NC).

Results

Maternal, Prenatal, and Labor & Delivery Characteristics

From 39,757 live births in the Tri-County area to Tri-County residents in 2003 and 2004, 628 labor and delivery records were selected for review, of which 622 (99%) were reviewed. The remaining six charts were not available upon request. The distribution of maternal characteristics and prenatal care and labor and delivery markers is shown in Table 1. The proportion of births among women younger than 20 years did not differ by race or ethnicity and the proportion of births among women over 35 years did not differ by race. However, births among women over 35 were three times more likely to occur among non-Hispanic women (95% Confidence Limit [CL] 1.2, 7.9). Excluding women of other or unknown race, black women were 2.4 times more likely (CL 1.1, 5.3) and Asian women were 2.8 times less likely (CL 1.1, 6.7) than white women to receive Medicaid assistance; Hispanic women were 3.4 times (CL 2.2, 5.3) more likely to receive Medicaid assistance than non-Hispanic women; and women younger than 20 years of age were 2.8 times more likely (CL 1.4, 5.4) to receive Medicaid assistance than women over 20 years.

Table 1: Distribution Maternal, Prenatal Care, and Labor & Delivery Characteristics.

	Weighted Estimate % (95% CL)
Maternal Characteristics	
White	82.7 (79.7, 85.7)
Asian / Pacific Islander	9.9 (7.5, 12.3)
Black	4.6 (2.9, 6.2)
Other / Unknown	2.8 (1.4, 4.2)
Hispanic	18.5 (15.6, 21.4)
<20 Years	6.3 (4.3, 8.3)
20-35 Years	82.6 (79.5, 85.7)
>35 Years	11.1 (8.6, 13.6)
Medicaid	25.2 (21.9, 28.6)
Prenatal Care	
Any Prenatal Care	99.7 (99.2, 100.0)
Inadequate	9.2 (6.8, 11.5)
Intermediate	32.9 (29.1, 36.7)
Adequate	57.9 (53.9, 61.9)
Labor & Delivery	
Gestational Age < 32 wks	1.7 (0.6, 2.9)
Gestational Age 32-36 wks	6.9 (4.8, 9.0)
Gestational Age ≥ 37 wks	91.4 (89.0, 93.7)
Birthweight <1500g	1.7 (0.6, 2.9)
Birthweight 1500-2499 g	5.0 (3.2, 6.9)
Birthweight 2500-3999 g	81.8 (78.6, 85.0)
Birthweight ≥ 4000 g	11.4 (8.9, 14.0)
Vaginal Delivery	68.8 (65.1, 72.6)
C-section	24.2 (20.7, 27.8)
Other Delivery	6.9 (4.9, 8.9)
Prolonged ROM	7.3 (5.1, 9.4)
Maternal Temp >38ºC	4.4 (2.8, 6.1)
Chorioamnionitis	2.8 (1.4, 4.2)

Whereas race was not associated with differences in prenatal care, Hispanic women, women younger than 20 years, and women receiving Medicaid assistance had reduced adequacy of prenatal care. For instance, 10.9% of Hispanic women had inadequate, 45.6% had intermediate, and 43.5% had adequate care, compared with 9.2% inadequate, 29.8% intermediate, and 61.0% adequate among non-Hispanic women (p=0.0030); 19.3% of women younger than 20 years had inadequate, 47.8% had intermediate, and 32.9% had adequate prenatal care, compared with 8.8% inadequate, 31.8% intermediate, and 59.3% adequate among women 20 years and older (p=0.0047); and 12.2% of women receiving Medicaid

assistance had inadequate, 46.8% had intermediate, and 41.0% had adequate prenatal care, compared with 8.6% inadequate, 28.1% intermediate, and 63.3% adequate among women not receiving Medicaid assistance ($p<0.0001$). No other prenatal care indicator was associated with maternal demographic characteristics.

Pre-term delivery (less than 37 weeks gestation) was associated with having had a previous preterm infant (OR 3.6; CL 1.3, 10.0), Cesarean section (OR 3.2; CL 1.8, 6.1), prolonged rupture of membranes (ROM) (OR 3.6; CL 1.6, 8.3), and suspected chorioamnionitis (OR 4.2; CL 1.1, 15.3) in respective univariate models. In a multivariable model with these variables, having had a previous pre-term infant, delivery by Cesarean section, and prolonged ROM remained significantly associated with pre-term delivery.

Group B Streptococcal Disease Screening

Table 2: Proportion of women screened for GBS and distribution of GBS screening results.

	Weighted Estimate % (95% CL)
Women Screened for GBS	85.8 (83.0, 88.6)
<35 Weeks	15.4 (12.2, 18.6)
35-37 Weeks	59.1 (54.9, 63.4)
>37 Weeks	25.4 (21.7, 29.2)
Screening Culture Results	
Positive	20.4 (16.8, 23.9)
Negative	78.9 (75.3, 82.5)
Not Documented	0.7 (0, 1.4)

Over four-fifths of women were screened for GBS colonization prior to delivery (Table 2). Among these women, the majority were screened for GBS colonization during 35-37 weeks gestation. One-fifth of women screened for GBS had positive culture results, with no difference seen in the proportion of screened women with a positive culture by gestational age at time of screening. Including women that had not been screened and those with undocumented culture results at the time of delivery, 14.8% (CL 12.0, 17.6) of all women had an unknown GBS culture status.

Women receiving no or inadequate prenatal care were 3.7 times (CL 2.0, 7.0) less likely to have been screened for GBS than women receiving intermediate or adequate prenatal care and women with preterm or threatened preterm delivery were 6.5 times less likely (CL 3.6, 11.9) to have been screened for GBS colonization than women delivering at full term. Over a third of (35.7%; CL 23.2, 48.1) women with preterm deliveries were not screened for GBS or had undocumented GBS screening results. No maternal characteristics predicted whether or not women were screened for GBS. Among women screened, those with preterm or threatened preterm delivery were 4.4 times (CL 1.9, 10.2) less likely to have been screened at 35-37 weeks gestation than women delivering at full term; no other differences were seen in the timing of screening among maternal and prenatal care factors. Additionally, the proportion of screening tests with a positive result did not differ by maternal or prenatal care factors.

Intrapartum Antibiotic Prophylaxis

Overall, 23.4% (CL 20.0, 26.9) of women had an indication for which IAP was recommended, including those with a positive GBS screening culture, preterm delivery, prolonged ROM, or maternal intrapartum temperature >38.0ºC that could indicate amnionitis (Table 1). Of these women, 77.2% (CL 70.2, 84.2) received IAP. Among women with an indication for IAP, those who did not receive IAP did not differ significantly from those who did, with respect to any maternal or prenatal care factors. The distributions of antibiotics administered and documented reasons for administering IAP are shown in Table 3. When IAP was administered for GBS prophylaxis, the most common antibiotics administered were penicillin (76.9%; CL 69.7, 84.2), clindamycin (13.6%; CL 6.8, 20.3), and ampicillin (7.7%; CL 3.8, 11.6).

Table 3: Distribution of Type and Reason for Administration of IAP.

	Weighted Estimate % (95% CL)
Antibiotic Administered	
Ampicillin	13.1 (7.5, 18.6)
Cefazolin	1.8 (0, 3.9)
Clindamycin	10.9 (5.6, 16.2)
Erythromycin	3.3 (0.2, 6.5)
Penicillin	62.0 (54.3, 69.8)
Vancomycin	0.5 (0, 1.3)
Other Antibiotic	44.5 (38.2, 50.7)
Reason for Administration	
GBS Prophylaxis	74.9 (67.5, 82.2)
Suspected Amnionitis	9.1 (4.1, 14.1)
Other Reason	12.4 (6.9, 18.0)
Unknown Reason	2.4 (0, 4.8)

Overall, 11.3% (CL 8.7, 13.9) of women had a documented allergy to penicillin. Among women with an indication, 73.3% (CL 71.4, 86.3) of women without a documented penicillin allergy received IAP, compared to 67.5% (CL 48.0, 86.9) of women with a documented penicillin allergy, a non-significant difference (p=0.24). Of women with a documented penicillin allergy, 84.3% (CL 69.2, 99.3) received clindamycin, 11.8% (CL 0, 26.7) received erythromycin, and 4.0% (CL 3.7, 4.3) received vancomycin. Antimicrobial susceptibility testing to clindamycin and erythromycin was performed on 3.5% (CL 0, 7.1) of isolates from women with positive GBS screening results before delivery. Of these, all were susceptible to clindamycin and three-quarters were susceptible to erythromycin. All women for whom susceptibility testing results were available received clindamycin.

Table 4: Association between indication for and receipt of IAP and Early- and Late-Onset GBS disease.

	aOR (95% CL)
Early-Onset	
IAP Indication	13.5 (2.7, 67.3)
IAP Administered	0.1 (0.01, 0.9)
Late-Onset	
IAP Indication	11.1 (2.0, 62.6)
IAP Administered	0.6 (0.1, 3.1)

Impact of GBS Screening and IAP on Disease Indicators

Included among the medical records reviewed were seven in which birth was followed by the development of early-onset (EO) GBS disease in the infant and 14 in which birth was followed by the development of late-onset (LO) disease. In multivariable models, having an indication for which IAP was recommended was predictive of infant EO-GBS disease, while receipt of IAP demonstrated a protective effect (Table 4). While having an indication for IAP was also predictive for LO-GBS disease, receipt of IAP was not significantly associated with this indicator. Four of the seven (unweighted, 57%) EO-GBS cases occurred in women who were appropriately managed, per the 2002 revised guidelines for the prevention of perinatal GBS

disease (Table 5), including three women without an indication who did not receive IAP and one woman with an indication who did receive IAP.

Table 5: Maternal GBS Screening and IAP Characteristics of EO-GBS Cases.

Case	Screened for GBS	Result of Screening	Other IAP Indication*	Receipt of IAP
1	**Yes**	**Positive**	**No**	**Yes**
2	**Yes**	**Negative**	**No**	**No**
3	**Yes**	**Negative**	**No**	**No**
4	**Yes**	**Negative**	**Yes**	**No**
5	Yes	Positive	Yes	No
6	Yes	Positive	Yes	No
7	Yes	Positive	No	No

*Includes pre-term delivery, prolonged rupture of membranes, and/or intrapartum fever ≥100.4ºF.
Bold indicates cases screened and provided IAP in accordance with the 2002 revised guidelines.

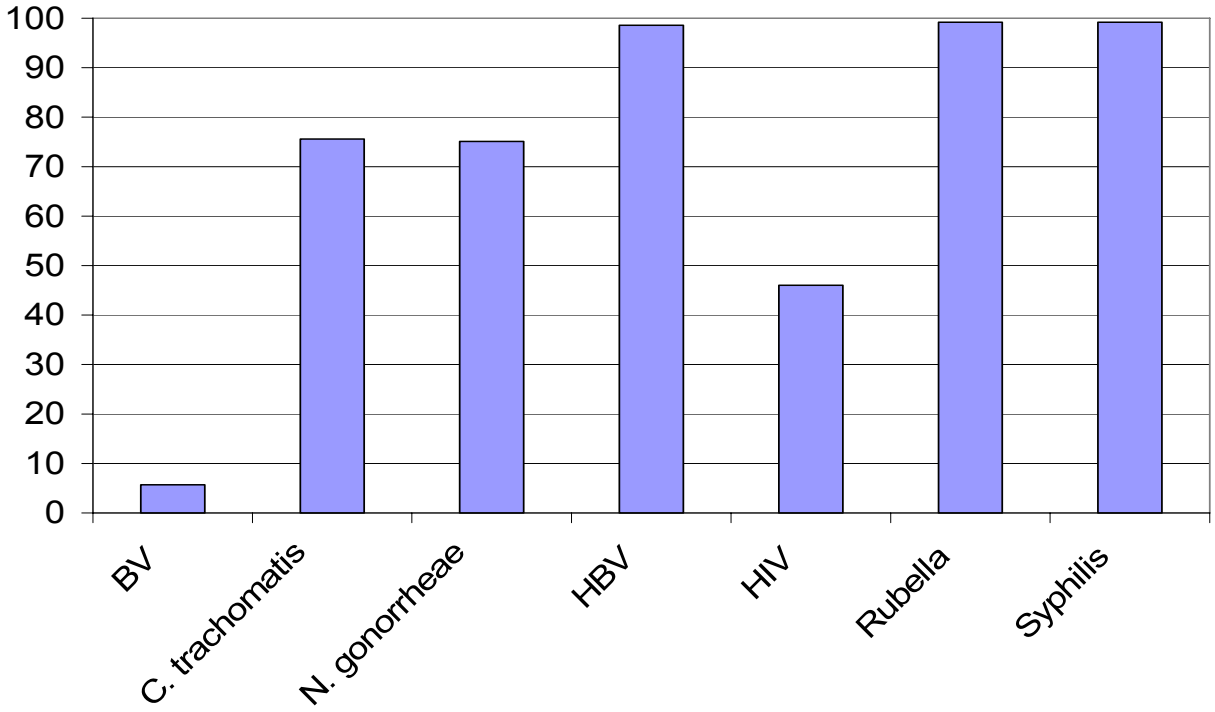
Screening and Prevention Indicators for Other Perinatal Disease

The proportions of pregnant women screened prior to admission for perinatal infections other than GBS, as indicated by their respective recommendations, are shown in Figure 1. The proportion of women screened for BV (5.7%; CL 3.9, 7.6) was not different between those with and without threatened pre-term labor (p=0.55). By maternal characteristics, Black women were more likely to be screened for BV than White women (p=0.0009), Hispanic women were more likely to be screened than non-Hispanic women (p=0.01), and women receiving Medicaid assistance were more likely to be screened than those not receiving assistance (p=0.0073). Almost three-fourths of those screened (64.7%; CL48.5, 80.7) had a positive diagnosis, 94.8% (CL 83.5, 100) of whom were treated. Among those with a positive diagnosis, the proportion of women delivering a pre-term infant did not differ between those who received treatment for BV and those who did not.

Three-fourths (75.6%; CL 72.3, 78.9) of all women were screened for *C. trachomatis* at least once, with Hispanic women and women receiving Medicaid assistance more likely to be screened than their respective comparison groups ($p<0.05$ for each). While the proportion of women younger than 25 screened at all for *C. trachomatis* was not significantly higher than that among women 25 and older, the former group was 5.6 times (CL 2.1, 15.2) more likely to have had two screening tests than the latter group. Women receiving Medicaid assistance were also more likely to have had two screening tests (OR 3.0; CL 1.2, 7.7). Screening was documented on or before the first prenatal care visit for 71.5% (CL 67.3, 75.6) of women, with the remainder screened during a later prenatal care visit. Among those screened, nine had positive *C. trachomatis* results, all of whom were treated for infection.

The profile for *N gonorrheae* screening was similar to that for *C. trachomatis*: 75.1% (CL 71.8, 78.4) were screened at least once, with Hispanic women and women receiving Medicaid assistance more likely to be screened than their respective comparison groups ($p<0.05$ for each). Women under 25 and women receiving Medicaid assistance were also more likely to have been screened twice (OR 5.1; CL 1.7, 15.3 and OR 3.0; CL .1, 8.3, respectively) than their respective comparison groups. Screening for *N. gonorrheae* was documented on or before the first prenatal care visit for 71.6% (CL 67.6, 75.8) of women, with the remainder screened during a later prenatal care visit. Among those screened, one woman had positive results and was treated for infection.

Figure 1: Proportion of women screened[†] for bacterial vaginosis (BV), *C. trachomatis*, *N. gonorrheae*, Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV), rubella, and syphilis prior to delivery.



[†]For BV, value refers to the proportion of women at risk for pre-term labor and for HIV, value refers to the proportion of women offered HIV testing prenatally; the remaining values refer to the total proportion of women screened for the respective infections. All values are weighted estimates.

Screening for HBV, rubella, and syphilis was almost universal, with nine women not screened for HBV, one woman not screened for rubella, and five women not screened for syphilis. In addition to the nine births among the women not screened for HBV, six infants were born to women with positive HBV screening results; three of these infants (unweighted, 20%) were noted in the maternal chart to have received the birth dose of HBV vaccine. Sixty-five women had susceptible, equivocal, or not-documented results of rubella screening, 48 (unweighted, 74%) of whom were vaccinated against rubella prior to discharge after delivery. Among screened women, those who were vaccinated against rubella prior to discharge were not significantly different than those who were not with respect to maternal or prenatal care factors.

Almost half (46.0%; CL 42.2, 49.8) of all women were offered an HIV test, of whom 20.7% (CL 16.2, 25.2) refused. Black women, Hispanic women, and women younger than 35 years of age were more likely to have been offered an HIV test than White women, non-Hispanic women, and women 35 years and older, respectively ($p<0.05$ for each). Among those offered an HIV test, Hispanic women and women receiving Medicaid assistance were more likely to refuse HIV testing if offered than other women, respectively. Ultimately, 36.5% (CL 32.8, 40.1) of women were tested for HIV, with Hispanic women less likely to have been tested than non-Hispanic women (OR 0.4; CL 0.3, 0.6). HIV testing was documented on or before the first prenatal care visit for 29.8% (CL 26.3, 33.3) of those tested and during a later prenatal care visit for 6.3% (CL 4.4, 8.3) of those tested; timing for HIV testing was not documented for 63.8% (CL 60.2, 67.40 of women. Results of maternal HIV testing were not ascertained.

Discussion

The 85% of Oregon women screened for GBS colonization prior to delivery is similar to findings from the other ABCs surveillance sites taking part in this evaluation and demonstrates rapid adoption of the revised guidelines to prevent EO-GBS disease within a year after their release (Schrag, unpublished data). This is especially true in Oregon where, in 1998-1999, only a quarter of women were screened for GBS – the lowest proportion screened among any of the sites [11]. The uptake of universal screening recommendations is credited with decreasing the national incidence of EO-GBS disease to the expected level of 0.32 per 1,000 live births [11,13]; in Oregon, its incidence decreased 30% from 0.11 cases per 1,000 live births during 2000-2001 to 0.08 per 1,000 live births during 2003-2004 (Unpublished surveillance data).

Despite this success, our results indicate missed opportunities and areas of improvement for the prevention of perinatal GBS disease in Oregon. For instance, since preterm infants have the highest incidence of EO-GBS disease, the 2002 guidelines recommend intrapartum antibiotic prophylaxis to women with threatened preterm delivery and an unknown GBS colonization status; yet, over a third of these women in our evaluation did not receive such prophylaxis [12]. As demonstrated by the proportion of cases occurring among women with an indication for intrapartum antibiotic prophylaxis, but without its receipt, improvements in this area may demonstrate the most promise for further reducing the occurrence of EO-GBS disease. One additional area of improvement is the type of antibiotic administered to women with a documented penicillin allergy. For women at low risk for anaphylaxis, this recommended agent changed in the 2002 guidelines from clindamycin to cefazolin, as the latter has a similar action as penicillin, but without documented resistance (Schrag, unpublished data). That 85% of such women continued to receive clindamycin – with none receiving cefazolin – demonstrates a need for continued education for appropriate antibiotic use among providers.

The four cases (57%) of EO-GBS disease that occurred in Oregon infants of women managed in accordance with the 2002 revised guidelines can be considered as prevention failures. While this is similar to the 61% reported from across all ABCs sites, it highlights the need for greater understanding of factors leading to such failures (Unpublished data). For instance, as half of these cases occurred in infants of women who were screened at the recommended time (35-37 weeks gestation) and had documented negative results, more research into false negative results is needed.

Our finding of near universal screening and treatment for several perinatal infections, such as HBV, rubella, and syphilis demonstrate successful adherence to the respective prevention guidelines among prenatal care providers in Oregon. Since 2007, all perinatal HBV cases among infants born to HBV surface antigen positive have been in infants who did receive immunoglobulin and the entire vaccine series, however, supporting the low occurrence of prevention failures (Unpublished surveillance data). While the proportion of neonates receiving the birth dose of HBV among those with an indication is low in this survey, it likely represents an underestimate of this indicator as hospitals may not record the infant's birth dose in the maternal medical record and we did not review infant medical records as a part of this study. At the very least, however, it highlights a potential area for further programmatic review to ensure providers are not missing this important prevention opportunity.

Further potential for missed prevention opportunities is evidenced by our findings with regard to screening practices for *C. trachomatis*, *N. gonnorheae*, and HIV. The profile of higher proportions of non-white and lower socio-economic status women screened for all three

infections is consistent with previous literature and likely reflects risk-based screening needs on the part of health care providers. Specifically regarding HIV testing, it is interesting to note that only 35% of women were tested for HIV and none were tested at admission. This very closely matches estimates obtained from reviewing birth certificate information and is lower than estimates obtained through studies of self-reported prenatal HIV screening practices, suggesting that women may have information about their HIV status that is not recorded in the medical record. Regardless, these data support the need for further provider education to increase adherence to universal prenatal screening recommendations for sexually transmitted infections.

Prenatal screening guidelines and treatment recommendations are effective in preventing vertical transmission of infections and, consequently, in preventing significant perinatal morbidity and mortality. Whereas surveillance programs can monitor the occurrence of perinatal infections, periodic evaluations such as the one detailed in this report are necessary to document uptake of new – and adherence to ongoing – prenatal screening and treatment practices. Future surveys of practices in Oregon will be necessary to evaluate revised GBS prevention guidelines, expected in 2010, to determine if screening practices for HIV have changed with the implementation of opt-out testing legislation in this state, and to confirm continued adherence of healthcare providers to screening practices for other perinatal infections.

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