
Corresponding Author:
Ms. Judy S Cohain,
CNM, Independent Researcher, Alon Shvut 37, 90433 - Israel

Submitting Author:
Ms. Judy S Cohain,
CNM, Independent Researcher, Alon Shvut 37, 90433 - Israel

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Author(s): Cohain J S

Abstract

Protocols recommending routine culture of women at 35-36 weeks pregnancy and treating GBS positive women with IV antibiotics in labor are loosely based on low level observational studies. Penicillin resistant GBS strains have been identified since 2006. All forms of GBS disease: EOS, late onset, adult and symptomatic GBS vaginitis are increasing since the strong enforcement of CDC protocols in the US. The short and long term effects of wide routine prophylactic use of antibiotics on healthy mothers and their newborns have not been analyzed. 35-36 weeks cultures have low specificity. Current CDC protocols appear to have a bias towards routine antibiotic prophylaxis without careful consideration of short and long term effects of their recommendations.

Review

As any midwife who attends waterbirth, one usually notices fecal matter floating in the water before the baby emerges. My reaction, knowing that GBS normally inhabits the intestinal tract was to theorize that waterbirths might have a higher rate of newborn infection due to being born in feces soiled water. Therefore, for births in bathtubs not pools, I used to always let the water out of the bathtub seconds before the baby emerged to avoid contact of the baby with the water. When I reviewed the published data however, what I found surprised me.

A review of the literature shows that birthing the fetus into water has the lowest rates of Early Onset Newborn GBS (EOGBS). A single case of early onset newborn GBS was reported among 4,432 hospital births in the absence of antibiotic prophylaxis (1,2) suggesting a 300% lower rate of EOS among low risk women giving birth into water compared to 1/1,450 currently for hospital births into air where CDC protocols are adhered to (3). Possible theories to explain this might be:

1) Inoculating the baby with mother’s intestinal flora at birth is protective;
2) Bath water dilutes GBS acquired during the descent among a multitude of competitive intestinal bacteria;
3) EOS is prevented by lower level of interventions and kangaroo care at water birth promoting maternal/fetal immune function.

From the data in hand, the most effective way to prevent EOS is to deliver a baby is into very warm water. However, this was not the conclusion of the Center for Disease Control in Washington, which reviewed the same data yet, recommends culturing all women at 35-36 weeks and treating the GBS positive ones with 5 million units of Penicillin intravenously (loading dose) and 2.5 million units of Penicillin every 4 hours after that until delivery.

The protocols recommended by the CDC are not supported by RCT evidence. There are few RCT studies as to whether screening women for GBS improves newborn outcomes, however the 4 that there are did not show any advantage to culturing women at 35-36 weeks.(4) In the early 1990s, an association was first observed, between a possible lowering of newborn GBS that took place when Penicillin was widely used in labor. EOS is still not a reportable disease in most states so rates are only known for certain places. Small studies tried giving newborns antibiotics, but that increased the perinatal mortality over newborns not given antibiotics usually as a result of necrotizing enterocolitis. Small studies tried giving women oral or IM antibiotics during pregnancy to decrease GBS, but the GBS was found to readily return. Finally the idea for culturing women at 35-36 weeks was suggested and treating those that were GBS positive at 35-36 weeks in labor. Before routine
prophylaxis, it was loosely estimated that 1.5/1000 babies, including preemies and all high risk women, got EOGBS disease. Since CDC began reporting, the overall incidence of early onset GBS disease of the newborn showed an initial downward trend from 2000-2003 (0.52 to 0.31 cases per 1,000 live births-premature and full term) followed by an increase from 2003-2006 (0.31 to 0.40).(3) The decrease only occurred among white full term babies. Data provided by the CDC (Figure 4) shows a small 2000-2007 decrease in EOGBS only among full term white infants (0.4 to 0.3/1000) while the rate in preterm black increased (1.6 to 2.4/1000), the rate of EOGBS in white preterm and term black infants stayed the same, and GBS disease among non pregnant adults increased.(pg23). In addition, the overall rate when high and low risk cases of EOGBS disease are added together decreased 1.7 (1990) to 0.4/1000 (2005) may not be caused by prophylactic antibiotics but could be explained by other lifestyle, environmental, social welfare etc improvements. Support for this comes from data showing an overall decrease in perinatal deaths, during the same period, in which perinatal deaths decreased from 9/1000 (1990) to 7.4/1000 (1996) to 6.6/1000 in 2005 (5). EOGBS only accounted for a total of (160 annual deaths in 1996) and 88 of a total 26,000 perinatal deaths in 2009. Therefore, perinatal death rates are decreasing as a general rule, due to many factors, other than antibiotic prophylaxis for GBS.

In November 1996, the first 2 studies were published looking at how long GBS cultures are accurate for. In 2002, the CDC revised its “Once GBS, Always GBS” protocols based on one of the studies which looked at 165 women who cultured positive at 35-36 weeks or closer to birth and found about 85% of these women were still positive at delivery.(6) The CDC ignored the outcomes of the other 1996 study (7) which found GBS cultures taken 24 hours before the woman gives birth to only agree 30% of the time with cultures taken 24 hours later, at the time of birth. Further research has continued to find that the 35-36 week culture is less than 90% accurate meaning 10% of women will be treated with antibiotics despite being negative for GBS at birth and another 10% who are actually GBS positive at birth will not be treated. A larger study in 2006 study(8) found the culture results of the 1283 subjects showed a sensitivity of 65%, specificity 90%. 10% of the GBS negative antenatal group converted to positive at the time of labor. (8) An even larger study in 2010 study among 1472 patients found the sensitivity was 51%, specificity 94%, positive predictive value 67%, and negative predictive value of 88%. (9) Despite a lack of support for the accuracy of 36 week GBS cultures at the time of birth, the 2010 CDC protocols continue to recommend acting on a 35-36 week culture. 

Reports of Penicillin resistant GBS began five years ago, and were published in 2007 (10). If Pen-Resis GBS follows the evolution of Pen-Resistant Strep pneumoniae which was first isolated in 1972(11), in 24 years or 2035, 50% of GBS will be not be susceptible to Penicillin(12). If the evolution of Pen-Resistant GBS were to resemble the development of MRSA, in 2055, 50% of GBS will be unsusceptible to Penicillin(13). Prolonged ROM is a known risk factor for EOS, yet there is no recommendation to eliminate routine AROM during labor. The CDC try to defend AROM as being irrelevant by stating definitively “GBS can cross intact amniotic membranes.” with no scientific citation to back it up. A study of 550 babies born to GBS positive women, by CS without ROM, and without prophylaxis, (14) demonstrated not a single case of GBS disease, where one would expected 5 sick newborn if GBS crossed membranes, supporting the theory that GBS never crosses intact membranes. In vitro study has not been able to demonstrate GBS crossing membranes, even at concentrations of 1,000,000,000 CFU. (15) Further investigation into how GBS could cross intact membranes demonstrated that GBS failed to invade amnion cells under a variety of assay conditions (16) and fetal membranes demonstrated an inhibitory effect on GBS. (17). Cases of colonized infants born by CS in the absence of ruptured membranes could be due to any number of other vectors other than the mother that come in contact with the baby.

Over 6 vaginal exams significantly increased rates of GBS disease(18). Scalp electrodes double the risk of GBS colonization of amniotic fluid (19) CDC recommendations do not include a recommendation to eliminate or even restrict vaginal exams and scalp electrodes. 

Outcomes of research on Chlorhexidine (pg4) state “randomized clinical trials have found no protection against early-onset GBS disease or neonatal sepsis.” The studies cited are from Soweto (20) and Pakistan (21) using a never pretested protocol of ‘swabbing the vagina once with a cotton ball with chlorhexidine 0.5% solution’. A quick swabbing is highly unlikely to have an effect on the colonization of GBS in the vagina, was never tested in any pretest, and indeed, had no effect. In the Soweto birthing population in which 26% of the birthing population is HIV positive, 35/1000 newborns had EOGBS disease despite 10% of them receiving correctly dosed prophylactic Penicillin whereas only 1.7/1000 newborns had EOGBS in the US before culture-based protocols were even established, and a third of that after. The data presented points to the
vast majority or all of EOGBS being correlated with immune suppression, not the absence of antibiotic prophylaxis. However the CDC blames maternal colonization with GBS, rather than immune suppression, despite the lack of evidence for this. Allicin, known to kill GBS in vitro since 1985 (22), is not given a single mention in CDC protocols, even though it is advantageous in its ability to not provoke antibiotic resistant mutant strains.

Conclusion(s)

The CDC protocols reflect a bias towards giving widespread prophylactic antibiotics that is not based on concrete evidence of improved outcomes in the short term or long term. All types of GBS disease are increasing where this protocol is enforced. Risk management protocols have shown equal outcomes while lowering the risk of the spread of antibiotic resistance. Evidence supports eliminating artificial rupture of membranes as well as routine vaginal exams. The evidence to date, demonstrates that the risk of EOS for full term pregnancy may be best lowered by birthing into hot water in the absence of antibiotic prophylaxis.

References

Illustrations

Illustration 1

A protocol for lowering Early Onset GBS would have to include eliminating routine AROM
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