Informed Consent: Group Beta Streptococcus

The issue of GBS is complex and the decision to test for colonization should begin with the material received from the midwife and also includes but is not limited to discussion, research, knowledge and your personal opinion of the risks and benefits. This informed consent contains information that has already been provided to you and is a reiteration for you to make a *signed* and documented choice. You may withdraw your consent at any time prior to the procedure.

Iff GBS is found to be positive in the urine, it is considered to be a serious urinary tract infection and can lead to other complications and more urgent forms of treatment should be discussed.

A. Purpose of Procedure
B. Description of Procedure
C. Risks, benefits, and uncertainties of the procedure
D. Reasonable alternative procedures
E. Consequences of not accepting the proposed procedure

A. Purpose of Procedure

Group B Streptococcus (GBS) is a normal bacterium that lives in the intestinal tracts of many healthy people. It is not a sexually transmitted disease but can be transferred sexually. Between 35 and 37 weeks of pregnancy, it is considered the medical standard of care to test for "highly colonized/positive" GBS. Being positive for GBS is found normally in 15-40% of women.

If GBS infects a newborn, serious complications can arise within hours of birth. GBS infection can cause pneumonia, meningitis, and death. If an infant needs to be treated for sepsis due to GBS, a NICU admission is necessary along with antibiotics, repeated blood draws, lumbar punctures and separation from the mother. About 50% of GBS infections are considered serious.

Risk of infection for the newborn:

- If a GBS+ mother does not receive antibiotics: 1 in 200
- If a GBS+ mother receives antibiotics: 1 in 4,000

It has been identified that there is increased risk with the following conditions:

- UTI from GBS during pregnancy
- Previous baby with GBS disease
- Fever during labor
- Rupture of membranes 18 hours or more before birth
- Pre-term delivery
- Routine obstetrical interventions: vaginal examinations, stripping membranes, artificial rupture of membranes.

The statistics provided above do not exclude or provide a breakdown of the risk factors listed. Additionally, all of the studies performed to obtain the statistics were performed in a hospital setting.

B. Description of Procedure

Test: This test is performed by taking a swab of the vagina/rectum. The swab is sent to a laboratory where they will determine and report if there is <10,000 CFU of GBS colonization. If there is >10,000 CFU, then

this is considered testing positive. You have the option to swab yourself or have it done for you – studies show that both methods are equally effective.

IV: An IV is performed during active labor that contains antibiotics. If more than one dose is necessary, there is the option to have a lock placed or to have the tubing removed between doses.

C. Risks, benefits, and uncertainties of the procedure
Risks: **Test:** The procedure for GBS testing itself is considered minimally invasive. Since there is the introduction of a foreign swab, there is risk of introducing a potential bacteria or foreign substance, although the swab is sterile.

IV: If the client elects IV antibiotics in labor, risks are infection at the site, anaphylaxis from the antibiotic used. Other mentionable risks are the potential increased risk of contributing to antibiotic resistance and increased incidence of non-GBS pathogens.

Benefits: **Test:** Knowing GBS Status. **IV:** Reduced risk of neonatal GBS infection.
Uncertainties: There is no known 100% test to determine GBS colonization, at one point you can test positive and then another point you can test negative. There is no perfect answer to whether or not GBS will affect a newborn; regardless of positive or negative testing. The procedure may involve risks to you and/or baby which are currently unforeseeable.

D. Reasonable alternative procedures
There are no known reasonable alternative procedures for testing of GBS. Some alternative suggestions have included Hibiclens douching, increase probiotics, vaginal garlic suppositories. If these are elected, a retesting should be accomplished and some of these methods may need to be performed in labor.

E. Consequences of not accepting the proposed procedure
o Hospital management in case of transfer.
o Not knowing risk status of infant possibly contracting EOD.
o No treatment provided for GBS positive colonization.

I understand that the CDC, AAP, ACOG guidelines are that vaginal and rectal GBS screening cultures should be performed at 35-37 weeks' gestation on all pregnant women except for those who had GBS in the urine during the current pregnancy or gave birth to a previous infant with invasive GBS disease; these patients should receive prophylaxis, regardless of the result of any vaginal culture. Patients should receive intrapartum prophylaxis if they meet any of the following criteria: (1) a history of a previous infant with invasive GBS disease, (2) the occurrence of GBS bacteriuria during the current pregnancy, or (3) a positive GBS screening culture during the current pregnancy. Patients with an unknown GBS status (culture not done or not ready) should receive intrapartum prophylaxis if delivery is < 37 weeks' gestation, if rupture of membranes is >/= 18 hours, or if the intrapartum temperature is >/= 100.4º F (38º C).
I have also read and understood the GBS handout provided to me. I have had my questions answered to my satisfaction and can make an informed choice regarding GBS testing. I accept full responsibility for my decision.

Statement of Choice

_____ I have chosen to be cultured for Group B Streptococcal Infection and, if positive, will consider my options after getting the test results.

_____ I have chosen to be cultured for Group B Streptococcal Infection and, if positive, will elect administration of antibiotics during labor.

_____ I have chosen to be cultured for Group B Streptococcal Infection and, if positive, will pursue alternative forms of treatment compatible with homebirth, even though this approach has not been proven to be more effective than the administration of antibiotics during labor. I also will re-test for GBS after alternative treatment is ensued.

_____ I have chosen NOT to be cultured for Group B Streptococcal Infection and ask my midwife to inform me if she feels that I have any increased risk factors for GBS.

Client's Signature Printed Name Date

Partner's Signature Midwife's Signature

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