Women’s Health

Point-of-Care Group B Strep Test Gets Approved

BY SHERRY BOSCHERT
San Francisco Bureau

MONTEREY, CALIF. — A newly approved rapid test for group B streptococcal (GBS) colonization in pregnancy can be performed by labor and delivery nurses and generates results in about an hour and a half, Dr. Rodney K. Edwards reported.

The Xpert GBS assay is the first rapid test approved for group B streptococcal (GBS) screening at the point of care and may improve GBS detection and prophylactic treatment at the time of labor, potentially reducing the incidence of early-onset neonatal GBS infection, he said at the annual meeting of the Infectious Diseases Society for Obstetrics and Gynecology.

The test was approved by the Food and Drug Administration on July 25 and is commercially available now. Conventional GBS screening by culture at 35-37 weeks’ gestation misses subsequent colonization. Results aren’t available for 14-48 hours, so culture isn’t helpful in around the clock, added Dr. Edwards of the University of Florida, Gainesville. He is a speaker for Cepheid, the company that funded the study.

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The test is made to be processed using Cepheid Xpert Dx system, which costs about $20,000.

One physician in the audience suggested that replacing culture screening with Xpert GBS screening would require doing an intrapartum assay on every woman. “It’s a paradigm shift on labor and delivery units,” he said.

Dr. Edwards said that initially the assay was used for women in labor without a prior screening culture—people who come in for premature rupture of membranes or preterm labor, or unregistered patients, he suggested. An eventual replacement of the assay for the current screening strategies could significantly increase the work of labor and delivery nurses. The nurses at his institutions liked doing the assay in the study, however, because they felt that it improved clinical care. “Our nurses now miss it and continue to ask me, ‘When is that machine coming back?’ ”

The assay is a qualitative, automated real-time polymerase chain reaction (PCR) test with fluoroscopic detection of the amplified DNA. Unlike other PCR tests, it doesn’t require that the sample be separately prepared and is designed to purify, concentrate, detect, and identify targeted nucleic acid sequences from unprocessed samples.

The study’s analysis excluded results from another 244 swabs—12 from patients who were enrolled more than once, 10 from patients with “unresolved” results after two attempts at Xpert GBS assay, and 222 that were vaginal/perianal swabs instead of vaginal/recanal swabs recommended by the CDC.

The investigators did analyze results from the excluded swabs, however, and found that the Xpert GBS assay was significantly less sensitive using vaginal/perianal swabs compared to vaginal/recanal swabs. “I have no idea why this is the case,” said Dr. Edwards. “It makes no sense to me,” and an additional study is planned comparing screening of vaginal/recanal and vaginal/perianal samples. He said the sensitivity of culture did not significantly differ between types of swabs.

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