False test results seen in maternal screening

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(AP) -- A massive effort to test pregnant women for a deadly germ they can spread to their babies has yielded a bad surprise - a high rate of wrong test results that led some infants to miss out on treatment.

A study found the test missed more of the infections than would normally be expected. If the mothers had tested positive for the Group B strep bacteria, they would have been given antibiotics during labor to cut the chances of infecting their infants.

Group B strep is a common bacteria carried in the intestines or lower genital tract, and can be spread to babies during delivery. It's harmless to most adults but in newborns can lead to blood infections, pneumonia, meningitis, mental retardation or hearing and vision loss, and death.

It is a rare problem which occurs in less than 1 in 3,000 births, but the infection's terrible risks drove the Centers for Disease Control and Prevention and doctor groups in 2002 to recommend routine tests of all pregnant women.

The study, led by the CDC, is the first large national study of the screening program. The CDC is planning follow-up research to pin down what caused the false negative test results.

Possible explanations include problems with the collection of samples or the accuracy of the standard lab test used to check for the germ, experts said. Or perhaps the mother was infected after getting the test.

"There are a lot of unknowns here," said Dr. Diane Ashton, deputy medical director for the March of Dimes.

No one is suggesting the screening program is a failure. The study found that screenings nearly doubled in only a few years. And infant infections from Group B strep, which were already dropping because of earlier prevention efforts, dipped another 27 percent.

"The guidelines have been an unabashed success," said Dr. Barbara Stoll, pediatrics chair at Emory University's medical school. She was not involved in the study, which is being published in Thursday's New England Journal of Medicine.

The new study is based on a database that tracks cases of Group B strep disease in 10 states. Over two years, 250 infants out of nearly 7,700 were born with the infection. The researchers also compared the results to a similar study done in the late 1990s, before the screening recommendations were in place.

The good news: The screening rate rose from 48 percent to 85 percent of pregnant women. And the antibiotics seemed to be very effective, said the CDC's Stephanie Schrag, a study co-author.

But Schrag and others acknowledged that the false negatives were a disappointing surprise.

Based on previous studies, the researchers calculated that they would see 44 to 86 cases of false negatives involving full-term infants. But the final study showed 116 cases - or about 60 percent of the infected full-term infants in the study were born to mothers who had been tested and mistakenly found clear of the infection.

The rest of the infected full-term babies were either not screened or

were born to mothers who tested positive.

Timing may be an issue. It's recommended that doctors test moms for the germ at 35 to 37 weeks into the pregnancy, by swabbing the vagina and rectum. But Group B strep infections can come quickly, and some tests might have been done before the bacteria appeared.

"Maybe it was a true negative test, and the mother later became colonized" with the bacteria, she said.

The study's authors said more rapid tests could make a difference, and development of a new vaccine against Group B strep could be an even better solution.