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Title **Rapid Testing for Group B Streptococcus During Labor: A Test Accuracy Study with Evaluation of Acceptability and Cost-Effectiveness**

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Aim

To determine the: *accuracy* (sensitivity, specificity, predictive values) of polymerase chain reaction (PCR) and optical immunoassay (OIA) technologies as rapid tests for maternal vaginal and rectal group B streptococcus (GBS) colonization at the onset of labor, using selective enrichment culture as the reference standard; *acceptability* of rapid testing for GBS colonization among pregnant women of different social and ethnic groups; and *cost and cost effectiveness* of rapid intrapartum testing for maternal GBS colonization to prevent early onset (EO) GBS disease, and compared this with other strategies for screening and prevention.

Conclusions and results

In all combinations of index and reference tests PCR was significantly more accurate than OIA in detecting maternal GBS colonisation. Combined vaginal or rectal swab index tests were more sensitive than either test considered individually (combined swab sensitivity for PCR 84% (95% CI 79%-88%); vaginal swab 58% (52%-64%); rectal swab 71% (66%-76%)). The highest sensitivity for PCR came at the cost of lower specificity (combined specificity 87% (95% CI 85%-89%); vaginal swab 92% (90%-94%); rectal swab 92% (90%-93%)). The sensitivity and specificity of rapid tests varied according to presence or absence of maternal risk factors, but not consistently. PCR results were determinants of neonatal GBS colonization, but maternal risk factors were not. Overall, the acceptability for rapid testing among participants was high, and no evidence showed that screening had raised anxiety. Vaginal swabs were more acceptable than rectal swabs.

Modeling analysis revealed that the most cost-effective strategy was to provide routine intrapartum antibiotic prophylaxis (IAP) to all women without prior screening. Since this was deemed unlikely to be acceptable to most women and midwives, the analysis was repeated without this strategy. Here, the most cost-effective screening was based on culture testing at 35 to 37 weeks' gestation, with antibiotics provided to all women who screened positive (assuming all women in premature labor received IAP). The results were sensitive to very small increases in costs and changes in other assumptions.

Recommendations

Although PCR performed better than OIA, neither rapid test was sufficiently accurate or cost effective to recommend in routine clinical practice. Rectal swabbing was less acceptable and the technologies need to be further refined for point-of-care use. The most cost-effective approach to reducing EO GBS disease is likely to be IAP for all women without prior testing. If this strategy is discarded on grounds of acceptability, IAP directed by screening at 35 to 37 weeks' gestation, with IAP to all premature laboring women, becomes cost effective. At present, it would be premature to suggest the implementation of either strategy.

Methods

See Executive Summary link at www.hta.ac.uk/project/1388.asp.

Further research/reviews required

The relative effectiveness, feasibility, and acceptability to women of screening by enriched culture and provision of routine IAP should be explored. Further refinements in rapid tests would be required to improve accuracy and make point-of-care testing practicable and cheaper, but would require further evaluation and comparison with existing strategies.

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