Three biomarker tests to help diagnose preterm labour: a systematic review and economic evaluation

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Declared competing interests of authors: Andrew Shennan is an investigator in a number of trials/studies related to preterm birth (the GlaxoSmithKline-funded NEWBORN tocolytic trial, the National Institute for Health Research-funded PETRA and QUIDS prediction studies, the Guy's and St Thomas' charity-funded EQUIPPT, the preterm management study and Tommy's charity-funded preterm birth studies). These studies include comparing PartoSure™ (Parsagen Diagnostics Inc., Boston, MA, USA) and the quantitative Fetal Fibronectin (fFN) Test (Hologic, Inc., Marlborough, MA, USA) and have been supported by free PartoSure samples from QUIAGEN and received financial support from Hologic, Inc. (fFN), paid to his institution to cover expenses of this comparison only. He has given lectures to internal staff at BioMedica [Actim® Partus (Medix Biochemica, Espoo, Finland)] and Hologic, Inc. (fFN), in the last 5 years and received financial support to cover expenses only for this when travelling to the USA and Finland.

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Plain English summary

Biomarker tests to diagnose preterm labour

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Infants may suffer from health problems if they are born early. If a mother has symptoms of labour before her baby is due, a test could be used to predict if the symptoms are real or a false alarm. A test could help the doctor to decide whether the mother needs treatment or to move to a specialist hospital or if she could be sent home (if it is a false alarm).

Our report compares three tests [PartoSure™ (Parsagen Diagnostics Inc., Boston, MA, USA), Actim® Partus (Medix Biochemica, Espoo, Finland) and the Fetal Fibronectin (fFN) Test (Hologic, Inc., Marlborough, MA, USA)] on how well they predict an early birth and how the costs and the long-term health outcomes of the child compare between and among tests.

All the published literature reporting the accuracy of the three tests and their costs was reviewed.

We developed a new cost-effectiveness model, which estimated the long-term health outcomes of the child based on the test results.

Twenty of the studies reviewed looked at how good the tests were at predicting an early birth within the next 7 days, and six looked at predicting birth within 48 hours. The designs of the studies and the women taking part in the studies varied greatly. This meant that comparing the accuracy of the tests was very difficult and it would be unfair to decide which test was the best.

Our model suggested no firm conclusions for the cost-effectiveness of fFN compared with Actim Partus. PartoSure appears to be less costly than Actim Partus and equally good at predicting preterm birth, but this is based on a study of very few patients. There were no data that allowed us to compare all three tests together.

The accuracy of the results is uncertain, mainly because all the studies are very different. We are aware of four related UK trials that are currently ongoing that plan to include large numbers of women.

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