High throughput, non-invasive prenatal diagnosis of fetal rhesus D status

Non-invasive prenatal diagnosis of fetal rhesus D status is a test which predicts the rhesus D genotype of a fetus from small fragments of fetal DNA that circulate freely in the plasma of pregnant women. During pregnancy, a woman who is rhesus D negative and carrying a rhesus D positive fetus may be exposed to small amounts of rhesus D antigen. This can cause an immune response in the mother; a process called sensitisation. This has no adverse health effects for the mother and usually does not affect the pregnancy during which it occurs. However, if the mother is exposed to the rhesus D antigen during a subsequent pregnancy, the immune response is quicker and much greater. The anti-D antibodies produced by the mother can cross the placenta and cause haemolytic disease of the fetus and newborn. Anti-D immunoglobulin is currently recommended to reduce the risk of sensitisation for all pregnant women who are rhesus D negative, as the rhesus D status of the fetus is unknown. However, rhesus D negative women carrying a rhesus D negative fetus gain no clinical benefit from this treatment. Non-invasive prenatal diagnosis of fetal rhesus D status may enable anti-D immunoglobulin to be given to rhesus D negative women with a rhesus D positive fetus, but be withheld from rhesus D negative women with a rhesus D negative fetus. The NICE diagnostics assessment programme will assess the clinical and cost-effectiveness of high-throughput, non-invasive prenatal diagnosis of fetal rhesus D status in order to make recommendations on its use in the NHS.