Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

This report summarises the existing evidence on the technology of interest in this Bevan exemplar application.

Topic:	**GENESIS PROJECT – genetic screening for fetal abnormalities in suspected miscarriages**
Topic exploration report number:	TER130

Aim of Search

Cedar researchers, on behalf of Health Technology Wales searched for evidence on the use of non-invasive prenatal testing (NIPT) for fetal genetic abnormalities in women who may be having a miscarriage in early pregnancy.

Summary of Findings

There is a substantial amount of evidence on the use of NIPT in early pregnancy to detect genetic abnormalities, but very little on the use of this technology in miscarriage.

No guidance documents or systematic reviews were identified which were relevant to this topic.

One relevant primary study was identified (Clark-Ganheart et al. 2015) and a non-systematic literature review (Reddy et al. 2012) which may be relevant.

One registered clinical trial was identified which has been published (Clark-Ganheart et al. 2015). Tommy's centre for miscarriage research is carrying out a relevant study but this does not appear to be registered.

Key Sources of Evidence

Clark-Ganheart CA, Fries MH, Leifheit KM, et al. (2015). Use of cell-free DNA in the investigation of intrauterine fetal demise and miscarriage. Obstetrics & Gynecology. 125(6): 1321-9.

Areas of Uncertainty

There is a limited amount of published evidence on the use of NIPT for detecting genetic abnormalities in miscarriage. No comparators of the intervention for results validation purposes were identified. It is also unclear which population would benefit the most from the intervention. No cost effectiveness studies were identified.

Brief literature search results

Resource	Results
UK guidelines and guidance	
Healthcare Improvement Scotland	We did not identify any relevant information from this source.
NICE	We did not identify any relevant information from this source.
Guidelines International Network	We did not identify any relevant information from this source.
Secondary literature and economic evaluations	
ECRI	Anora Miscarriage Test (Natera, Inc.) to Aid in Determining Cause of Pregnancy Loss Description: Genetic Test Product Brief -The Anora Miscarriage Test is a blood test intended to determine whether a miscarriage (also known as spontaneous abortion) was caused by fetal chromosomal abnormalities, especially in patients who have experienced recurrent miscarriages or have a history of fetal chromosomal abnormalities. Anora uses single-nucleotide polymorphism (SNP)-based chromosomal microarray (CMA) testing to detect certain chromosomal abnormalities.
Cochrane library	We did not identify any relevant information from this source.
Medline	We did not identify any relevant information from this source.
Primary studies	
Medline	Clark-Ganheart CA, Fries MH, Leifheit KM, et al. (2015). Use of cell-free DNA in the investigation of intrauterine fetal demise and miscarriage. Obstetrics & Gynecology. 125(6): 1321-9. Reddy UM, Page GP, Saade GR. (2012). The role of DNA microarrays in the evaluation of fetal death. Prenatal diagnosis. 32(4): 371-5.
Cochrane library	We did not identify any relevant information from this source.
Ongoing secondary research	
Clinicaltrials.gov	NCT01916928 The Use of Cell Free Fetal DNA in the Maternal Blood in the Evaluation of Intrauterine Fetal Demise and Miscarriage (Completed and Published). Tommy's centre for miscarriage research is carrying out a relevant study but this does not appear to be registered. Further information available at: https://www.tommys.org/our-organisation/research-by-cause/miscarriage/fetal-dna

Date of search:	06 August 2019
Concepts used:	Miscarriage OR pregnancy loss AND Cell free DNA OR fetal DNA OR cffDNA OR non invasive prenatal OR NIPT