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Horizon scanning prioritising summary

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Non-invasive fetal electrocardiogram (ECG): Routine examination of fetal heart rhythms.

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PRIORITISING SUMMARY

REGISTER ID: **0000055**

NAME OF TECHNOLOGY: **NON-INVASIVE FETAL ELECTROCARDIOGRAM (ECG)**

PURPOSE AND TARGET GROUP: **ROUTINE EXAMINATION OF FETAL HEART RHYTHMS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Experimental	☐	Established
☐	Investigational	☐	Established *but* changed indication or modification of technique
☐	Nearly established	☐	Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Cross sectional observational study, United Kingdom	✓		

IMPACT SUMMARY:

Doppler ultrasound, foetal electrocardiography (fECG) and foetal magnetocardiography are all methods which can monitor the fetal heart beat non-invasively during pregnancy. During labour, the fetal heart rate can be measured either by ultrasound or invasively by attaching an electrode to the baby's scalp. The fECG displays P (atrial contraction), QRS (ventricular contraction) and T (ventricular repolarisation) waves that correspond to electrical events. Cardiotocographic traces may be difficult to interpret due to maternal electrocardiography waveform and maternal abdominal muscular activity. This difficulty is accentuated due to the weakness of the fetal heartbeat. Multiple pregnancies present additional difficulties due to the need to separate more than one fetal signal during an ECG. Conventional fECG averages the heartbeat over three beats and may miss events such as arrhythmia. In addition, fECG has only 60% reliability (Crowe et al 2001). During labour, unnecessary obstetric intervention may occur due to the misinterpretation of electrocardiographs.

Taylor et al (2003), in association with the UK Ministry of Defence, has developed a new method for non-invasive ECG. This system utilises defence software technology that filters out "noise" to enable detection of specific targets. Twelve to sixteen electrodes (depending on singleton or multiple pregnancy) are placed on the mother's abdomen.
To monitor fetal progress during pregnancy a non-invasive fECG takes approximately 15-20 minutes (including an explanation of the process) or data may be continuously acquired during labour. An algorithm (QinetiQ) is used to process the signal and the generation of a non-invasive fECG report takes an additional 5-8 minutes. Taylor et al (2003) reported on 250 non-invasive fECG recordings obtained from 241 individuals carrying singleton babies.

Successful separation of signal was observed in 85% (213/250) of non-invasive fECGs. The majority of failed separations (31) occurred in fetuses between 27 and 36 weeks gestation. In twins and triplets, separate fetal signals were obtained in 78% (91/116) and 93% (14/15), respectively. This technique is currently under trial in two major London hospitals.

The AIHW reported the number of separations for the AR-DRG numbers associated with childbirth (caesarian and vaginal, with and without complications) as a total of 242,861 in the year 2001-02 (AIHW 2003).

There is currently no economic information available for this non-invasive fetal ECG.

CONCLUSION:

There is limited and low level evidence currently available for this experimental non-invasive fetal electrocardiography.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Neilson, J. P. (2003) In *The Cochrane Library*, Vol. 4 John Wiley & Sons Ltd, Chichester, UK.

Peters, M., Crowe, J. et al (2001). 'Monitoring the fetal heart non-invasively: a review of methods', *J Perinat Med*, 29 (5), 408-416.

Taylor, M. J., Smith, M. J. et al (2003). 'Non-invasive fetal electrocardiography in singleton and multiple pregnancies', *BJOG*, 110 (7), 668-678.

SEARCH CRITERIA TO BE USED:

Cardiotocography
Electrocardiography/*methods
Gestational Age
Heart Rate, Fetal/*physiology
Pregnancy
Pregnancy, Multiple/*physiology
Reference Values
Sensitivity and Specificity