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**Magnetic resonance imaging for the
detection of foetal abnormalities**

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The production of this *Horizon scanning prioritising summary* was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

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PRIORITISING SUMMARY

REGISTER ID: 000286

NAME OF TECHNOLOGY: MAGNETIC RESONANCE IMAGING FOR
DETECTION OF FOETAL ABNORMALITIES

PURPOSE AND TARGET GROUP: DETECTION OF FOETAL ABNORMALITIES

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- | | |
|--|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input checked="" type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- | | |
|--|-------------|
| <input type="checkbox"/> Yes | ARTG number |
| <input type="checkbox"/> No | |
| <input checked="" type="checkbox"/> Not applicable | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Austria		✓	
Israel		✓	

IMPACT SUMMARY:

In-utero magnetic resonance imaging (MRI) is gaining increased use in obstetric practice as an adjunct to ultrasound for diagnostic information. This summary presents current issues in the use of MRI for the detection of foetal abnormalities.

BACKGROUND

Previously the use of MRI for foetal imaging was limited by foetal motion. With the development of fast scan techniques, images can be obtained in less than one second and provide multi-planar views. MRI for foetal indications may be used for:

- clarification of abnormalities detected by ultrasound;
- when ultrasound imaging of a high-risk foetus may not be sufficient to detect an abnormality;
- further characterisation of complex anomalies that are not fully characterised by ultrasound;
- detection or exclusion of additional findings which may affect the diagnosis;
- management planning of delivery and perinatal care in high risk pregnancies;
- and

- management planning for foetal surgery.

The central nervous system (CNS) has been widely studied by MRI and suspected CNS abnormalities represent the most common indication for foetal MRI (Cannie et al 2006). MRI can provide structural, maturational and functional information. Foetal MRI imaging allows direct visualisation of both sides of the foetal brain whereas ultrasound imaging of the brain is often shadowed by overlying structures. An abnormality commonly diagnosed by MRI is ventriculomegaly, an excess of fluid in the lateral ventricles of the developing brain and may result in an increased risk of delayed neurological development (Salomon et al 2006 and Glenn and Barkovich 2006a). Ventriculomegaly is classified as severe when the axial diameter measured across the atrium of the ventricle exceeds 15mm. It is generally accepted that 10mm is the upper limit of the normal range.

Foetal MRI may also be performed to assess neural tube defects, congenital diaphragmatic hernia and masses that obstruct the foetal airway (Levine 2006). Other common indications for foetal MRI include suspected abnormalities of the corpus callosum and cerebellar vermis (Glenn and Barkovich 2006a). Approximately 75% of referrals for foetal imaging by MRI are for assessment of the foetal brain (personal communication 7th December 2006). Information provided by MRI may be used to assist parents in their decision to continue or discontinue a pregnancy, planning the mode of delivery or to plan for foetal surgery.

Current United Kingdom recommendations for the use of MRI in foetal imaging is to not duplicate diagnostic information gained from ultrasound (to reduce any potential risks), hence to use MRI only when it can aid in the diagnosis and improve counselling (Morris et al 2005). MRI is generally avoided in the first trimester due to the availability of limited safety data and an improved diagnostic accuracy with increasing gestational age (Glenn and Barkovich 2006a).

Foetal imaging with MRI can be performed on standard clinical MRI units and total examination time is between 45-60 minutes. Contrast agents are not required or recommended (Cannie et al 2006). During the procedure a surface coil is placed over the abdomen and pelvis and a sliding platform moves the mother into the MRI unit. Single-shot fast-spin techniques are employed for imaging.

CLINICAL NEED AND BURDEN OF DISEASE

The National Perinatal Data Collection reports there were 256,925 babies born to 252,584 mothers in Australia during the year 2003. Of these, there were 20,243 (7.9%) preterm births (less than 37 weeks gestation). During this same period, 5,345 babies were admitted to level III neonatal intensive care units, which equates to a rate of 21.0 per 1,000 live births (Laws and Sullivan 2005).

There is no *current* national data collection of birth defects in Australia. The most recent publication available reported a prevalence of 17 per 10,000 birth defects in the period 1981-1997 (AIHW 2006). In South Australia, amongst children born in 2002, the proportion of births with birth defects was 4.2 per cent, with notification of 747 cases to date (The South Australian Birth Defects Register 2005).

Mild cerebral ventriculomegaly occurs in approximately 0.15 and 0.7 per cent of pregnancies (Salomon et al 2006).

DIFFUSION

There are three centres in Victoria which currently perform foetal MRI in association with tertiary Maternity Foetal Medicine Units. In South Australia, MRI is in limited use for foetal indications. The literature accessed at the time of preparing this summary suggests that continued technical advances are likely to contribute to significant growth in the uptake of this technology (Glenn and Barkovich 2006b).

COMPARATORS

The standard screening imaging tool during pregnancy for foetal abnormalities is ultrasound between 18-20 weeks gestation.

EFFECTIVENESS AND SAFETY ISSUES

A recent study evaluated the contribution of MRI in the evaluation of borderline (10-to 12mm) ventriculomegaly (level III-2 diagnostic evidence). MRI confirmed the diagnosis in 106/185 cases (57%) previously detected with ultrasound and found other abnormalities in 5 (5%) of these 106 cases. MRI found ventricular measurement to be <10mm in 43/185 (23%) cases and >12mm in 36/185 (19%) cases. A ventricle size of >12mm was detected in 36 fetuses, and of these, six (17%) had other abnormalities. No other abnormalities were detected in the 43 cases with a ventricle size <10mm. The application of MRI was found to modify case management in five per cent of cases with borderline ventriculomegaly (Salomon et al 2006).

In one study (level III-2 diagnostic evidence) MRI results were compared in 100 pregnancies in which CNS abnormalities had been previously detected on ultrasound (Whitby et al 2004). Ultrasound and MRI provided identical results in 52 cases. In 35 cases MRI either changed the diagnosis (29) or gave extra information (6 cases) that could have changed management. In 11 cases MRI did not confirm abnormalities previously detected by ultrasound. The authors highlight the significance of this finding as the parents had decided to terminate in two of these cases if the MRI confirmed the ultrasound findings.

In an earlier study (level III-2 diagnostic evidence) the effect of foetal MRI on changes in diagnosis, patient counselling, and case management of fetuses suspected of having central nervous system (CNS) anomalies was examined. In this study 69/214 (32.2%) fetuses had normal findings and 39/214 (18.2%) were referred for CNS abnormality. Ultrasound confirmed abnormal findings in 145/214 (67.8%) fetuses. Changes in counselling and management after MR are summarised in Table 1 (Levine et al 2003).

Table 1 MRI Changes in Counselling, Diagnosis, and Management*

Ultrasound CNS diagnosis	N	MRI changed counselling (%)	MRI changed diagnosis (%)	MRI changed management (%)
Normal	69	13 (19)	3 (4)	2 (3)
Normal, but CNS anomaly suspected by US findings	9	7 (78)	4 (44)	3 (33)
Mild ventriculomegaly	28	5 (18)	5 (18)	1 (3)
Moderate ventriculomegaly	18	8 (44)	7 (38)	1 (5)
Severe ventriculomegaly	9	6 (66)	5 (55)	3 (33)
Arachnoid cyst	14	12 (86)	5 (36)	3 (21)
Spinal neural tube defect	21	5 (24)	2 (9)	1 (5)
Encephalocele	9	7 (78)	5 (55)	4 (44)
Dandy Walker variant/malformation	16	8 (50)	4 (25)	3 (19)
Small head	4	4 (100)	4 (100)	3 (75)
Vascular malformation	3	3 (100)	1 (33)	3 (100)
Holoprosencephaly	4	1 (25)	1 (25)	0 (0)
Megacisterna magna	2	2 (100)	0 (0)	0 (0)
Miscellaneous	8	5 (63)	3 (38)	2 (25)
Total	214	86	49	29

An MRI diagnosis of ventriculomegaly in 54 fetuses resulted in 17 changes in diagnosis, 19 changes in counselling, and five changes in management. Of the 145 fetuses with CNS abnormalities, MRI findings changed the diagnosis in 32% and there was a change in maternal counselling in 50% of cases. The mean gestational age (GA) of fetuses with abnormal findings and change in counselling (26 weeks) was significantly higher than in those with abnormal findings and no change in counselling (23 weeks). In 27/145 cases, there was a change in case management. These changes included a decision to terminate (n=13, mean GA: 20 weeks), continue pregnancy (n=4, mean GA: 19 weeks), direct the mode and/or location of delivery (n=5, mean GA: 30.5 weeks) and direct perinatal care (n=5, mean GA: 30 weeks). There was a significant difference in the gestational ages of fetuses in these four groups ($p < 0.01$) (Levine et al 2003).

COST IMPACT

There are no studies assessing the cost impact of implementing foetal MRI as an adjunct.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There are few studies on the long-term effects in children who have undergone foetal MRI imaged in-utero (Glenn and Barklovich 2006a). In the United Kingdom the National Radiation Protection Board (NRPB) and the Medicines and Healthcare Products Regulatory Agency (MHRA) do not recommend MRI in the first trimester (Morris et al 2005). MRI screening is recommended only if it is deemed advantageous to the management of mother or foetus and that these benefits outweigh the theoretical risks. The American College of Radiology provide similar guidelines for the use of foetal MRI. Informed consent would need to explain that although no risks are known it cannot be demonstrated that no risk exists.

OTHER ISSUES The correct interpretation of foetal MRI scans requires a multidisciplinary team of radiologists, foetal medicine and perinatal specialists (Cannie et al 2006, and personal communication).

At the time of preparing this summary a basic search in PUBMED for related articles on foetal MRI revealed numerous reviews of its use and emerging applications. An internet search found abstracts presented at First International Congress and Second International Course on Fetal MRI in May 2006, which described the potential role of MRI in imaging areas other than CNS including foetal lungs, gallbladder, colon and urinary tract (Ultrasound Obstet Gynecol 2006).

CONCLUSION:

The results of foetal MRI imaging, whether verifying presence or absence of abnormalities, or discovering new abnormalities not detected by ultrasound have shown to affect clinical decision making. At the time of preparing this prioritising summary it was advised that there is increasing interest in and acceptance of its prenatal use in clinical practice in Australia.

HEALTHPACT ACTION:

MRI for the detection of foetal abnormalities is currently being conducted in several centres in Victoria, with all outcome data to be collected. HealthPACT recommended that this technology be monitored to assess the Victorian results.

SOURCES OF FURTHER INFORMATION:

(2006). 'Fetal Abstracts of the First International Congress on Fetal MRI, ' Conference Proceeding: The First International Congress and Second International Course on Fetal MRI, Natural History Museum, Vienna, Austria, In: *Fetal Abstracts of the First International Congress on Fetal MRI, Ultrasound Obstet Gynecol*, Volume 27, (5), 471-597,

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- Whitby, E. H., Paley, M. N. et al (2004). 'Comparison of ultrasound and magnetic resonance imaging in 100 singleton pregnancies with suspected brain abnormalities', *BJOG*, 111 (8), 784-792.

LIST OF STUDIES INCLUDED

Total number of studies	
Level III-2 diagnostic evidence	3

SEARCH CRITERIA TO BE USED:

Central Nervous System Diseases/diagnosis/embryology
 Fetal Diseases/ diagnosis
 Gestational Age
 Humans
 Magnetic Resonance Imaging
 Prenatal Diagnosis/ methods/standards