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Horizon Scanning Technology Prioritising Summary

MR colonography

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AHTA

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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This Horizon scanning prioritising summary was prepared by Adrian Purins, Linda Mundy, and Professor Janet Hiller from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Discipline of Public Health, School of Population Health and Clinical Practice, Mail Drop 545, University of Adelaide, Adelaide, SA, 5005.

PRIORITISING SUMMARY

REGISTER ID: **000355**

NAME OF TECHNOLOGY: **MR COLONOGRAPHY**

PURPOSE AND TARGET GROUP: **BOWEL CANCER DIAGNOSIS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL:

☒	Yes	Many MRI units have TGA approval. Specific software may be required to be able to perform MR colonography.
☐	No	
☐	Not applicable	

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Netherlands	✓		
USA	✓		
Germany	✓		
Denmark	✓		

IMPACT SUMMARY:

Hospitals or specialist medical clinics would provide this diagnostic service to patients undergoing investigation for colon cancer. MR colonography is a non-invasive imaging technique that does not expose the patient to ionising radiation such as in CT colonography. While conventional MR colonography requires bowel preparation some newer algorithms allow the use of either faecal tagging or masking agents and minimal bowel preparation. Such advances may make MR colonography more acceptable to the target populations as a bowel cancer diagnostic tool.

BACKGROUND:

The Australian federal government has recently initiated the National Bowel Cancer Screening Program. This screening program uses the faecal occult blood test (FOBT)

and is available to Australians turning 55 or 65 during the period 1 May 2006 to 30 June 2008. Test positive subjects are currently investigated with colonoscopy, an invasive procedure which requires bowel preparation[1]. Colonoscopy carries the small but significant risk of transfusion requirement after polyp removal (1 in 500), perforation (1 in 1000) or death (1 in 10 000) (Viiala et al 2003). Virtual colonoscopy (VC) is based on non-invasive imaging technologies which allow a graphical, three dimensional representation of the bowel to be constructed. It is then possible to virtually inspect the bowel for suspicious growths. If such growths are discovered, conventional colonoscopy and biopsy are performed. Being non-invasive, VC overcomes many of the risks inherent in conventional colonoscopy. Virtual colonoscopy techniques such as CT colonography are currently available in the Australian health system. Another new method of virtual colonoscopy uses magnetic resonance imaging (MRI) as the imaging technique; this is termed Magnetic Resonance colonography (MR colonography). This new application of MRI is non-invasive and does not expose the patient to ionising radiation, unlike CT colonography. In addition, MR colonography has a potentially higher resolution than CT colonography. Recent advances in MR colonography allow minimal bowel preparation by using specific tagging or masking agents such as a bright-lumen strategy (gadolinium for faecal tagging and a water-gadolinium mixture for rectal filling) or a dark-lumen strategy (barium for tagging and water for rectal filling). These tagging methods allow the faecal material to be removed from the final image leaving just the well defined bowel wall in the image.
MR colonography is intended as substitute for colonoscopy. Colonoscopy is used as a screening tool in other countries. As Australia uses the FOBT for screening, MR colonography is more likely to be used, not as a screening tool, but as a diagnostic method for patients that test positive in the FOBT.

CLINICAL NEED AND BURDEN OF DISEASE:

Colorectal cancer is the second most common cancer in Australian men and women. There were 12,977 new cases of colorectal cancer in Australia in 2004. In 2005 there were 4,113 deaths in Australia caused by colorectal cancer. Colorectal cancer incidence rates have been increasing in real terms for the period from 1993 to 2003, up 27 per cent, but when age adjusted, the incidence shows a small drop of 1.5 per cent over the same period (AIHW 2007a; AIHW 2007b).

DIFFUSION:

No evidence of diffusion of this technology into Australia was found.

[1] Bowel preparation varies but usually includes strict dietary requirement and administration of laxatives to remove stools and cleanse the bowel.

COMPARATORS:

The gold standard for bowel cancer screening is a FOBT and if this is positive further diagnosis is performed with a colonoscopy. Performing a FOBT biennially may reduce the risk of dying from bowel cancer by one third (DOHA 2007) and may save up to 2,000 lives per year (Macrae 2005). Colorectal cancer screening by FOBT followed by colonoscopy has been shown to be cost effective (Gow 1999; Macrae 2005).

SAFETY AND EFFECTIVENESS ISSUES:

MR colonography research is currently focussed on several areas, such as optimal image acquisition parameters, faecal tagging methods to avoid full bowel cleansing, and comparisons to standard colonoscopy.

A study involving 200 patients (mean age 58 years) with personal or family history of colorectal polyps or cancer to investigated MR colonography versus conventional colonoscopy as diagnostic methods. Patients were at high risk of colorectal cancer and were consecutively recruited from clinics performing standard colonoscopy. Patient bowel preparation was limited to a low fibre diet, a stool softener (Lactulose), and a tagging agent (gadolinium). The MR colonography was performed within two weeks prior to the standard colonoscopy. MR colonography diagnosis was performed blinded to the results of the standard colonoscopy by two observers who did not confer. Only polyps of 10mm or larger were counted as positive. Colonoscopy detected 22 polyps meeting this criterion in 12 patients. Combined observer data for MR colonography gave a per patient sensitivity of 75 per cent [95% CI 43, 95] and a specificity of 93 per cent [95% CI 89, 97]. Combined observer polyp level sensitivity was 77 per cent [95% CI 48, 93]. Overall the observers reported a 93 per cent agreement on polyps 10 mm or larger (Florie et al 2007) (Level III-2 diagnostic evidence).

An unselected population of subjects older than 50 yrs (315 patients) was screened using MR colonography with standard colonoscopy used as the reference standard. Subjects were randomly selected from an insurance provider clientele (n=660). Of these, 441 (median age 63 years) entered the trial, with 94 abandoning the trial after MR colonography and before colonoscopy. MR images were not acquired in five patients due to difficulties with the technique. Bowel preparation was limited to ingestion of a faecal tagging agent (5.0% Gastrografin, 1.0% barium sulphate, 0.2% locust bean gum). At the time of MR colonography the bowel was distended by administration of a water enema. Standard colonoscopy detected 235 lesions and MR colonography detected 67 of these, giving a sensitivity of 28.5 per cent. When only lesions of 10mm or larger were included sensitivity was 73.9 per cent. At a per patient level, of the 121 patients diagnosed positive by standard colonoscopy, 44 were positive by MR colonography (sensitivity 36.4 %). For larger lesions (≥10mm) the sensitivity increased to 70 per cent. Faecal tagging and MR colonography allowed

diagnostic quality images in more than 90 per cent of colonic segments examined. Motion artefacts and insufficient faecal tagging reduced the image quality to below diagnostic quality in 9.4 per cent of segments. Using MR colonoscopy, 22 patients were diagnosed as having a colorectal lesion which was not confirmed by standard colonoscopy. When these patients were re-examined by standard colonoscopy 19 were found to be negative for lesion presence, thus MR colonography gave 19 false positives at the patient level (specificity 90.2 %). When only lesions >10 mm were considered the specificity of MR colonography was 100 per cent (Kuehle et al 2007) (Level III-2 diagnostic evidence).

A retrospective study investigating whether patient characteristics could influence the imaging effectiveness of MR colonography, analysed 333 (mean age 61 years) subjects from a normal asymptomatic population. Faecal tagging was performed using ingestion of 250 mL of a contrast solution (5% Gastrogra-fin®, 1% barium and 0.2% locust bean gum) with each regular meal. It was found that 95 per cent of colonic segments were able to be adequately imaged using MR colonography, however increasing subject age lead to poorer faecal tagging. A questionnaire was answered by 254 of the 333 patients approached and 89 per cent of respondents indicated that they did not find the tagging protocol to be inconvenient (Kinner et al 2007a) (Level III-3 diagnostic evidence)..

An important factor for a screening technique is patient acceptance of the procedure. Several studies examined patient preference when tested with conventional colonoscopy and MR colonography. In a study of 30 consecutive subjects undergoing both techniques, preference of either for a future test was examined. MR colonography was preferred by 66 per cent of subjects, with 10 per cent preferring colonoscopy and 21 per cent had no preference (Achiam et al 2007) (Level III-2 diagnostic evidence)..

A second study investigated patient acceptance in an asymptomatic population of 284 patients (mean age 59 years). MR colonography with faecal tagging and standard colonoscopy was performed on the subjects. The subjects were asked to complete a questionnaire rating various aspects of MR colonography and standard colonoscopy. There was no significant difference between patient acceptance of either technique. MR colonography rated an average of 3.4 out of 10 (1 not unpleasant at all to 10 very unpleasant), while colonoscopy rated 3.0 out of 10. When asked to choose a future test modality, 44 per cent favoured standard colonoscopy and 46 per cent favoured MR colonography (Kinner et al 2007b) (Level III-2 diagnostic evidence)..

One study reported that a colonoscopy had to be aborted due to a bowel perforation with the patient requiring immediate surgical repair (Kuehle et al 2007). No other safety information was reported in the remaining studies.

Several medium scale studies examined MR colonography compared to standard colonoscopy. Similar results were reported, with MR colonography having moderate

sensitivity and good specificity. MR colonography did not detect small lesions as efficiently as colonoscopy, although it performed well on lesions that are likely to be clinically relevant. MR colonography was deemed to be more or at least equally acceptable to subjects undergoing screening for bowel cancer. The evidence examined in this Prioritising Summary was of moderate quality, with no randomised trials reporting long term outcomes identified.

COST IMPACT :

No cost effectiveness information was found regarding MR colonography.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS:

No issues were identified/raised in the sources examined.

OTHER ISSUES:

No issues were identified/raised in the sources examined.

SUMMARY OF FINDINGS:

MR colonography, when compared to colonoscopy, has moderate sensitivity and good specificity. Patient acceptance of MR colonoscopy is at least equal to acceptance of colonoscopy. It is unclear where this test would be placed in Australian clinical practice where FOBT is used for screening the asymptomatic unselected population over the age of 55. Colonoscopy may be used as a diagnostic modality for higher risk (eg family history) individuals. Thus relevant studies for this review are those dealing with a high risk population.

HEALTHPACT ACTION:

The faecal occult blood test is currently used in Australia for population screening. Patients testing positive by FOBT undergo conventional colonoscopy and in cases where colonoscopy fails, CT colonoscopy may be utilised. Therefore HealthPACT has recommended that further assessment of this technology is no longer warranted.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level III-2 diagnostic evidence	4
Level III-3 diagnostic evidence	1

REFERENCES:

Achiam, M. P., Chabanova, E. et al (2007). 'Implementation of MR colonography', *Abdom Imaging*, 32 (4), 457-462.

AIHW (2007a). *Australian Cancer Incidence and Mortality (ACIM) books: Colorectal*, Australian Institute of Health and Welfare.http://www.aihw.gov.au/cancer/data/acim_books/colorectal.xls

AIHW (2007b). *Cancer in Australia: an overview, 2006,* Australian Institute of Health and Welfare.http://www.aihw.gov.au/publications/can/ca06/ca06.pdf

DOHA (2007). *What is screening?* [Internet]. Department of Health and Ageing. Available from: http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/what-is-screening [Accessed 25th March].

Florie, J., Jensch, S. et al (2007). 'MR colonography with limited bowel preparation compared with optical colonoscopy in patients at increased risk for colorectal cancer', *Radiology,* 243 (1), 122-131.

Gow, J. (1999). 'Costs of screening for colorectal cancer: an Australian programme', *Health Econ,* 8 (6), 531-540.

Kinner, S., Kuehle, C. A. et al (2007a). 'MR colonography with fecal tagging: do individual patient characteristics influence image quality?' *J Magn Reson Imaging,* 25 (5), 1007-1012.

Kinner, S., Kuehle, C. A. et al (2007b). 'MR colonography vs. optical colonoscopy: comparison of patients' acceptance in a screening population', *Eur Radiol,* 17 (9), 2286-2293.

Kuehle, C. A., Langhorst, J. et al (2007). 'Magnetic resonance colonography without bowel cleansing: a prospective cross sectional study in a screening population', *Gut,* 56 (8), 1079-1085.

Macrae, F. A. (2005). 'Screening for colorectal cancer: virtually there', *Medical Journal of Australia,* 182 (2), 52-53.

Viiala, C. H., Zimmerman, M. et al (2003). 'Complication rates of colonoscopy in an Australian teaching hospital environment', *Intern Med J,* 33 (8), 355-359.

SEARCH CRITERIA TO BE USED:

Colonoscopy/methods

Colorectal Neoplasms/ diagnosis/pathology

Hyperplasia/diagnosis/pathology

Intestinal Polyposis/diagnosis/pathology

Magnetic Resonance Imaging/ methods

Mass Screening/methods