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Australia and New Zealand Horizon Scanning Network

ANZHSN

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National Horizon Scanning Unit

Horizon scanning prioritising summary

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**Capsule endoscopy: For the diagnosis of
small bowel diseases.**

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Assessment*

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The production of these *Horizon scanning prioritising summaries* 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: 0000011

NAME OF TECHNOLOGY: CAPSULE ENDOSCOPY

PURPOSE AND TARGET GROUP: DIAGNOSIS OF SMALL BOWEL DISEASES

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 checked="" type="checkbox"/> Yes | ARTG number | 78651 |
| <input type="checkbox"/> No | <input type="checkbox"/> Not applicable | |

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or completed	Limited Use	Widely Diffused
ISRAEL	✓		
UK	✓		
USA			✓
GERMANY	✓		
ITALY	✓		
BELGIUM	✓		
AUSTRALIA		✓	

IMPACT SUMMARY:

Given Imaging Pty Limited provides wireless capsule endoscopy (M2A or “mouth-to-anus”) with the aim of improving the diagnosis of disease of the small bowel. M2A (various models) (product ID: 154084, Sponsor: Given Imaging Pty Limited) has TGA approval (ARTG No 78651). It received American FDA clearance in August 2001.

The radiotelemetry capsule endoscope (or video capsule) is small enough to be swallowed (11x27 mm) and has no external wires, fiberoptic bundles or cables. When swallowed by the patient, the capsule is propelled by peristalsis throughout the gastrointestinal tract and continuously transmits images at the rate of two frames per second for a period of up to seven hours. The patient need not be confined to a hospital or clinic during the examination and is free to continue their daily routine. The images are subsequently downloaded from the portable recorder for analysis. The time needed to evaluate the video sequence can range from 45 minutes to two hours depending on learning curve and the number of pathological abnormalities present.

The potential benefits of the technology are its comparative acceptability to patients and improved manoeuvrability, and therefore possibly better diagnostic imaging. Current imaging methods such as gastroscopy, small bowel endoscopy and colonoscopy are uncomfortable

because they require comparatively large diameter flexible cables to be pushed into the bowel. Small bowel endoscopy is particularly limited by problems of discomfort and failure to advance the endoscope far into the small bowel.

A study in the UK assessed the diagnostic accuracy of capsule endoscopy by cross-classifying patients with obscure or chronic gastrointestinal bleeding on capsule endoscopy and push enteroscopy. The capsule identified significantly more small intestinal bleeding sources than push enteroscopy ($p < 0.05$) (Mylonaki et al, 2003). In a similar study (Ell et al, 2002), capsule endoscopy had the highest diagnostic yield when compared to push enteroscopy and conventional diagnostic work-up. The main complication associated with capsule use occurs when the capsule is caught in the diverticulae or strictures of the intestine that are inaccessible to flexible endoscopic retrieval. The manufacturers of the M2A device also contraindicate its use in children or persons with pacemakers.

The number of claims processed by the HIC for the Medical benefits Schedule (MBS) item number 32090 (fiberoptic colonoscopy with or without biopsy) and MBS item number 32095 (endoscopic examination of small bowel) were 210,134 and 137 respectively, for the period July 2002 – June 2003.

CONCLUSION:

MSAC are currently conducting a full HTA on this technology.

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Schreyer, A. G., Golder, S. et al (2003). 'New diagnostic avenues in inflammatory bowel diseases. Capsule endoscopy, magnetic resonance imaging and virtual enteroscopy', *Dig Dis*, 21 (2), 129-137.

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SEARCH CRITERIA TO BE USED:

Comparative Study

*Endoscopes, Gastrointestinal

Endoscopy, Gastrointestinal/*methods/standards

Gastrointestinal Hemorrhage/*diagnosis

Capsules

Capsules/*diagnostic use

Intestinal Diseases/pathology

Intestine, Small/pathology

Radio Waves

Telemetry/*methods

Crohn Disease/*diagnosis/pathology