Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with
those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety and diagnostic yield of wireless capsule endoscopy appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 Clinicians should consider the use of other investigations prior to wireless capsule endoscopy, particularly in patients with Crohn's disease in whom strictures are suspected.

2 The procedure

2.1 Indications

2.1.1 The main indication for this procedure is obscure gastrointestinal bleeding, which is defined as bleeding of unknown origin that persists or recurs after a negative initial endoscopy (colonoscopy and/or upper gastrointestinal endoscopy). Diagnosis may be difficult because bleeding can often be slow and/or intermittent. Patients may experience prolonged blood loss, leading to iron deficiency (anaemia) and a feeling of tiredness. Another important indication is the diagnosis and investigation of Crohn's disease.

2.1.2 Bleeding from the small intestine can result from a number of conditions, including vascular lesions (angiodysplasia), small bowel tumours, and Crohn's disease (which may be suspected because of other symptoms).

2.1.3 There are several methods for evaluation of the small bowel, including
push enteroscopy (using a flexible endoscope through which images of the bowel's lining can be seen), intraoperative endoscopy and radiological small-bowel follow-through studies (in which the patient is required to drink barium and then have X-ray pictures taken of their abdomen at timed intervals). For most of these methods, the diagnostic accuracy (the ability to diagnose and exclude disease correctly) is poor.

2.2 Outline of the procedure

2.2.1 The patient swallows a small capsule, usually after an overnight fast. This capsule consists of a camera, a light source and a wireless circuit for the acquisition and transmission of signals. As the capsule moves through the gastrointestinal tract, images are transmitted to a data recorder worn on a belt outside the body. These data are transferred to a computer for interpretation. The capsule is then passed in the patient's stool and is not used again.

2.2.2 This procedure allows for the end-to-end visualisation of the small bowel. However, the presence of a motility disorder or stricture may preclude successful investigation.

2.3 Efficacy

2.3.1 The published evidence suggests that wireless capsule endoscopy can detect a bleeding source in 31–76% (4/13–25/33) of patients with obscure gastrointestinal bleeding. In all studies, wireless capsule endoscopy had a higher diagnostic yield (proportion of patients identified with an apparent abnormality) than the comparator test. However, in most cases, patients had undergone extensive prior investigations, which would be likely to decrease the apparent diagnostic yield for the comparator procedures. It was not possible to determine the relative diagnostic performance (ability to detect correctly both the presence and absence of disease) of wireless capsule endoscopy compared with alternative conventional diagnostic tests. Several studies reported that wireless capsule endoscopy findings had changed patient management, but limited details were given as to whether change in management improved health outcomes. For more details, refer to the
For suspected Crohn's disease, the evidence suggests that wireless capsule endoscopy identifies small bowel lesions suggestive of this diagnosis in 43–71% (9/21–12/17) of patients with normal findings on conventional tests. Three studies reported that wireless capsule endoscopy findings had changed patient management, with two studies reporting clinical improvement in 83–100% (10/12–9/9) of patients. The available evidence, however, is not of sufficient quantity and quality to determine the relative diagnostic performance of wireless capsule endoscopy compared with alternative conventional diagnostic tests in diagnosing unselected patients with suspected Crohn's disease. For more details, refer to the Sources of evidence section.

2.4 Safety

2.4.1 No significant complications were reported in the studies. The most commonly reported adverse events associated with the procedure were abdominal pain, nausea and vomiting. Delayed passage of the capsule was also reported in a number of studies but, in the majority of cases, this resolved without specific treatment. In a study of 200 patients performed to assess the complications associated with the use of wireless capsule endoscopy, six (3%) patients had complications associated with the procedure. These included two patients who experienced delayed passage and had to have surgery to remove the capsule, one patient who was unable to swallow the capsule and one patient who inadvertently aspirated the capsule. For more details, refer to the Sources of evidence section.

2.4.2 The Specialist Advisors considered this to be a safe procedure. They noted that the most likely adverse event was lodgement of the capsule in narrowed areas of the small bowel, causing bowel obstruction. One Advisor commented that this complication was more likely in patients with suspected Crohn's disease than in patients with obscure gastrointestinal bleeding.
2.5 Other comments

2.5.1 It was noted that there are other indications.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview to this guidance.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Update information

Minor changes since publication

January 2012: minor maintenance.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.