NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SCOPE

1 Guideline title

Gastrointestinal bleeding: the management of acute upper gastrointestinal bleeding

1.1 Short title

Acute upper GI bleeding

2 The remit

The Department of Health has asked NICE: 'To prepare a clinical guideline on the management of acute upper gastrointestinal bleeding'.

3 Clinical need for the guideline

3.1 Epidemiology

a) Upper gastrointestinal bleeding is defined as haemorrhage occurring at any point between the mouth and the duodenum; it is the most common emergency managed by gastroenterologists in the UK. Peptic ulcer disease is the most common pathology underlying upper gastrointestinal bleeding, occurring in 35–50% of cases. Variceal bleeding, accounting for 5–10% of cases, should be considered separately because of the special considerations required in its management. In approximately a fifth of cases no cause is found.

b) The overall incidence of acute upper gastrointestinal bleeding in the UK ranges from 50–150 per 100,000 of the population per year. Men are more commonly affected than women. Those in lower

socioeconomic groups are more commonly affected than those in higher groups. Incidence rises sharply with age, which is especially significant in the context of an ageing population. Increasing use of aspirin, clopidogrel and warfarin (particularly in older people who have vascular disease) poses particular problems. Non-steroidal anti-inflammatory drug (NSAID) usage is a well-recognised risk factor.

c) Upper gastrointestinal tract bleeding is estimated to account for 5000 deaths per year in the UK. In 1995 a major audit described a mortality of 11% in patients admitted to hospital with upper gastrointestinal bleeding, rising to 33% for patients already admitted to hospital who subsequently developed the problem. A similar audit in 2007 reported that the respective figures were 7% and 26% in the 6750 cases that they analysed.

3.2 Current practice

a) Patients on systemic non-steroidal anti-inflammatory drugs (NSAIDs) or cyclooxygenase-2 (COX-2) inhibitors, and acutely unwell patients in intensive care units, are at increased risk of developing acute upper gastrointestinal bleeding. Interventions exist that provide both primary and secondary prophylaxis. The current NICE guidance on osteoarthritis recommends that whenever systemic NSAIDs or COX-2 inhibitors are used, they should be co-prescribed with a proton pump inhibitor (PPI). However, in some settings (such as in an intensive care unit) the issue of prophylaxis is more contentious and guidance is needed. In addition, offering prophylactic strategies in intensive care units across the NHS might have economic implications.

b) Patients with suspected upper gastrointestinal bleeding are currently referred to secondary care services for further clinical assessment and investigation. Patients with cardiovascular compromise are resuscitated and stabilised before investigation. Blood products for resuscitation and the correction of coagulopathy

are not used in a standard way. For those with suspected chronic liver disease and upper gastrointestinal bleeding there may be a role for terlipressin acetate and intravenous antibiotic therapy before endoscopy.

c) Upper gastrointestinal endoscopy is the widely accepted diagnostic investigation of choice, but the optimal timing for this investigation is unclear. Service provisions for out-of-hours endoscopy are highly variable, and offering 24-hour endoscopy across the NHS would have serious economic implications. Appropriate indications for some therapeutic endoscopic interventions are well established and there has recently been increasing consensus regarding when and how the various methods for controlling bleeding should be deployed.

d) Major advances in therapy have occurred since the British Society of Gastroenterology issued the last national guidance in 2002 and there is significant opportunity to reinforce and build upon the SIGN guidance published in 2008. A recent UK-wide audit showed that compliance with standards of care (the use of blood products, deployment of investigations and management) for acute upper gastrointestinal bleeding is variable at best. A national guideline is needed on the prevention and management of acute upper gastrointestinal bleeding to address the uncertainties and variability in practice in primary and secondary care.

4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, ‘Further information’).

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

a) Adults and young people (16 years and older) with acute variceal and non-variceal upper gastrointestinal bleeding.

b) Adults and young people in high dependency and intensive care units who are at high risk of acute upper gastrointestinal bleeding.

4.1.2 Groups that will not be covered

a) Adults with chronic upper gastrointestinal bleeding.

b) Children (15 years and below).

c) Patients with a bleeding point lower than the duodenum.

4.2 Healthcare setting

a) Primary, secondary and tertiary care.

4.3 Clinical management

4.3.1 Key clinical issues that will be covered

a) Primary prophylaxis for acutely ill patients in high dependency and intensive care units.

b) Assessment of risks (such as mortality, rebleeding and the need for further intervention), including the use of scoring systems.

c) Initial management and resuscitation including:

- blood products
- proton pump inhibitors for likely non-variceal bleeding (pre- and post-endoscopy)

- terlipressin acetate and antibiotics for patients with likely variceal bleeding.

d) Timing of endoscopy.

e) Management of non-variceal upper GI bleeding including:

- endoscopic therapy (which modalities to use in combination)
- treatment options if a first endoscopic therapy has failed (angiography and embolisation, surgery, repeat endoscopy)
- control of bleeding and prevention of rebleeding in patients on NSAIDs, aspirin or clopidogrel.

f) Management of variceal upper GI bleeding including:

- treatment before endoscopy, including pharmacological therapy (antibiotics and terlipressin acetate, including duration of therapy)
- primary treatment for gastric varices (endoscopic injection of glue or thrombin and/or transjugular intrahepatic portosystemic stent shunt [TIPSS])
- interventions for uncontrolled bleeding (oesophageal or gastric) including balloon tamponade, TIPSS, surgery and repeat endoscopy.

g) Information and support for patients and carers.

h) Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

4.3.2 Clinical issues that will not be covered

a) Treatment for *Helicobacter pylori*.

4.4 Main outcomes

a) Mortality.

b) Re-bleeding.

c) Surgery.

d) Blood transfusion requirements.

e) Length of hospital stay.

f) Health-related quality of life.

4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY). However, in disease areas where the QALY is not ideal, another appropriate unit of effectiveness will be assessed. Furthermore the costs considered will usually only be from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

4.6 Status

4.6.1 Scope

This is the final scope.

4.6.2 Timing

The development of the guideline recommendations will begin in July 2010.

5 Related NICE guidance

5.1 Published guidance

- Unstable angina and NSTEMI. NICE clinical guideline 94 (2010). Available from www.nice.org.uk/guidance/CG94
- Stroke. NICE clinical guideline 68 (2008). Available from www.nice.org.uk/guidance/CG68
- Osteoarthritis. NICE clinical guideline 59 (2008). Available from www.nice.org.uk/guidance/CG59
- Acutely ill patients in hospital. NICE clinical guideline 50 (2007). Available from www.nice.org.uk/guidance/CG50
- MI: secondary prevention. NICE clinical guideline 48 (2007). Available from www.nice.org.uk/guidance/CG48
- Atrial fibrillation. NICE clinical guideline 36 (2006). Available from www.nice.org.uk/guidance/CG36
- Dyspepsia. NICE clinical guideline 17 (2004). Available from www.nice.org.uk/guidance/CG17
- Clopidogrel in the treatment of non-ST-segment-elevation acute coronary syndrome. NICE technology appraisal guidance 80 (2004). Available from www.nice.org.uk/guidance/TA80
- Wireless capsule endoscopy for investigation of the small bowel. NICE interventional procedure guidance 101 (2004). Available from www.nice.org.uk/guidance/IPG101

5.2 Guidance under development

NICE is currently developing the following related guidance (details available from the NICE website).

- Prevention of cardiovascular disease. NICE public health guidance. Publication expected April 2010.
- Alcohol use disorders: clinical management. NICE clinical guideline. Publication expected May 2010.

6 Further information

Information on the guideline development process is provided in:

- ‘How NICE clinical guidelines are developed: an overview for stakeholders' the public and the NHS’
- ‘The guidelines manual’.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).