

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

SCOPE

Clinical guideline title: Ulcerative colitis: the management of ulcerative colitis

Quality standard title: Ulcerative colitis: the management of ulcerative colitis

1 Introduction

1.1 *Clinical guidelines*

Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions in the NHS. They are based on the best available evidence.

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.

1.2 *Quality standards*

Quality standards are a set of specific, concise quality statements and measures that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of diseases and conditions.

For this topic a NICE quality standard will be produced based on the guideline recommendations. The clinical guideline and the quality standard will be published at the same time.

This scope defines the areas of care for which specific quality statements and measures will (and will not) be developed.

The guideline and quality standard development processes are described in detail on the NICE website (see section 7).

2 Need for guidance

2.1 *Epidemiology*

- a) Ulcerative colitis is an idiopathic chronic inflammatory disorder of the colon that has a relapsing remitting pattern. It is the most common type of inflammatory disease of the bowel, with an incidence of 10 per 100,000 people annually, and a prevalence of 243 per 100,000. This amounts to approximately 146,000 patients in the UK with a diagnosis of ulcerative colitis.
- b) Ulcerative colitis can present at any age but tends to have highest incidence in a bimodal distribution, with peaks between the ages of 15 and 25 years and between 55 and 65 years.
- c) Ulcerative colitis is a lifelong disease associated with significant morbidity, and the potential for social and psychological sequelae particularly if poorly controlled. An estimated 30–60% of people with ulcerative colitis will have at least one relapse per year. About 80% of these are mild to moderate and about 20% are severe. Symptoms of relapse include bloody diarrhoea, abdominal pain, anorexia, and weight loss.
- d) Approximately 25% of people with ulcerative colitis will have one or more episodes of acute severe colitis in their lifetime. Of these, 20% will need a colectomy on their first admission and 40% on their next admission. Although mortality rates have improved steadily over the past 30 years, acute severe colitis still has a mortality rate of up to 2%. Mortality is directly influenced by the timing of interventions, including medical therapy and colectomy.
- e) Elective pan-proctocolectomy can be an effective treatment for eliminating the symptoms of severe ulcerative colitis. However postoperative morbidity is associated with stoma care and ileoanal pouch use. Complications of pan-proctocolectomy include: decrease in female fertility, male impotency, pouchitis and small

bowel obstruction. Problems with urgency, leakage and nocturnal soiling may persist after surgery, and some patients may need a permanent ileostomy if ileal pouch anastomosis fails. Even in expert centres, pan-proctocolectomy has an operative mortality of between 1 and 4%, and postoperative lifelong morbidity of up to 15%.

- f) Ulcerative colitis has a well documented association with the development of colorectal cancer, with greatest risk in long-standing and extensive disease. Overall lifetime risk of colorectal cancer in people with ulcerative colitis is approximately 2.7%, with an annual incidence of dysplasia or cancer between 3.7 and 5.7%. Moreover, degree of colonic inflammation in ulcerative colitis is a predictor of dysplasia or cancer development. This emphasises the importance of adequate and effective control of disease activity to reduce the risk of colorectal cancer.

2.2 Current practice

- a) Current medical management centres on treating active disease and maintaining remission in an attempt to reduce both morbidity and mortality.
- b) Treatment of relapse may depend on the clinical severity, extent of disease and patient's preference and may include the use of aminosalicylates or corticosteroids. Preparations of aminosalicylates and corticosteroids are usually administered orally or per rectum; corticosteroids may be administered intravenously in acute severe disease.
- c) Most patients receive maintenance therapy with aminosalicylates. There may be variation in the doses of aminosalicylates and in whether a combination of treatment routes is used.
- d) People needing two or more courses of corticosteroids in a year may be started on second-line immunosuppressants such as

azathioprine or mercaptopurine unless contraindicated. It appears that azathioprine and mercaptopurine are increasingly used to maintain remission and reduce inflammation in people with long-standing ulcerative colitis.

- e) Some people may need 'rescue' therapy with intravenous ciclosporin if an acute severe colitis flare-up does not respond to standard first-line management with intravenous corticosteroids. Response rate is variable but an estimated 50% of patients at this stage will need either emergency colectomy, or semi-elective colectomy in the subsequent 6 months.
- f) Anti-TNF agents have been used as an alternative to ciclosporin for managing acute severe colitis over the past few years.
- g) The resulting wide choice of agents and dosing regimens has produced widespread heterogeneity in management across the UK, and emphasises the importance of comprehensive guidelines to help healthcare professionals provide consistent high quality care.

3 Clinical guideline

3.1 Population

3.1.1 Groups that will be covered

- a) Adults (18 years and older), young people and children with a diagnosis of ulcerative colitis.
- b) Consideration will be given to specific needs, if any, of:
 - children and young people (including transition between paediatric and adult services and puberty)
 - pregnant women.

3.1.2 Groups that will not be covered

- a) People with indeterminate colitis.

3.2 Healthcare settings

- a) NHS settings in which treatment for ulcerative colitis is delivered.

3.3 Management

3.3.1 Key issues that will be covered

- a) Drug therapy for the induction of remission for mild, moderate and severe active ulcerative colitis, and maintenance of remission, including the following drug categories:

- aminosalicylates
- corticosteroids
- immunomodulators – azathioprine, mercaptopurine, methotrexate, ciclosporin and tacrolimus.

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.

- b) Indications and timing of surgical management, specifically, ileoanal pouch surgery or total colectomy for acute severe colitis, recurrent relapses or continuous uncontrolled symptoms.
- c) Monitoring of bone health.
- d) Monitoring of growth in children.
- e) Information, education and support for people with ulcerative colitis and their families and carers.

3.3.2 Key issues that will not be covered

- a) Diagnosis.
- b) Treatment of extraintestinal manifestations of ulcerative colitis.

- c) Surgical techniques (except those listed in section 3.3.1 b).
- d) Reconstruction after previous surgery.
- e) Pouchitis.
- f) Management with:
 - antibiotics
 - fish oil
 - helminths
 - heparin as a primary treatment
 - leukapheresis
 - nicotine
 - probiotics.

3.4 *Main outcomes*

- a) Mortality.
- b) Remission and relapse.
- c) Health-related quality of life.
- d) Growth in children.
- e) Onset of puberty or pubertal development.
- f) Adverse events, including effects of treatment on fertility.
- g) Admissions to hospital (including length of stay).
- h) Surgery, specifically colectomy.

Outcomes for both paediatric and adult practice will be included if data is available.

3.5 *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), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see section 7).

4 Quality standard

Information on the NICE quality standards development process is available on the NICE website, see section 7.

4.1 Areas of care

The areas of care in a patient's journey that will inform the development of the quality statements are set out below. The content of the final quality standard may differ after consultation with stakeholders.

4.1.1 Areas of care that will be considered

- a) Treatment
 - Drug therapy for the induction of remission
 - Drug therapy for the management of acute and severe exacerbations of ulcerative colitis.

- b) Ongoing management
 - Drug therapy for the maintenance of remission
 - Nutrition support. See:
 - Nutrition support in adults. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/CG32

- c) Indications and timing of surgical management

- d) Identification and management of risks and complications
 - Fertility and pregnancy
 - Growth

- Monitoring of bone health
 - Risk of colorectal cancer. See:
 - Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. NICE clinical guideline 118 (2011). Available from www.nice.org.uk/guidance/CG118
 - Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005). Available from www.nice.org.uk/guidance/CG27 and scheduled for an update.
- f) Information, education and support for people with ulcerative colitis and their families and carers.

4.1.2 Areas of care that will not be considered

- a) Diagnosis.

4.2 *Economic aspects*

Developers will take into account both clinical and cost effectiveness when prioritising the quality statements to be included in the quality standard. The economic evidence will be considered, and the cost and commissioning impact of implementing the quality standard will be assessed.

5 Status

5.1 *Scope*

This is the final scope.

5.2 *Timings*

The development of the guideline recommendations and the quality standard will begin in September 2011.

6 Related NICE guidance

Published

- Infliximab for acute exacerbations of ulcerative colitis. NICE technology appraisal guidance 163 (2008). Available from www.nice.org.uk/guidance/TA163
- Infliximab for subacute manifestations of ulcerative colitis. NICE technology appraisal guidance 140 (2008). Available from www.nice.org.uk/guidance/TA140
(These two technology appraisals will be cross-referred to in the guideline as appropriate)
- Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. NICE clinical guideline 118 (2011). Available from www.nice.org.uk/guidance/CG118
- Medicines adherence. NICE clinical guideline 76 (2009). Available from www.nice.org.uk/guidance/CG76
- Irritable bowel syndrome in adults. NICE clinical guideline 61 (2008). Available from www.nice.org.uk/guidance/CG61
- Faecal incontinence. NICE clinical guidance 49 (2007). Available from www.nice.org.uk/guidance/CG49
- Injectable bulking agents for faecal incontinence. NICE interventional procedure guidance 210 (2007). Available from www.nice.org.uk/guidance/IPG210
- Nutrition support in adults. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/CG32
- Referral guidelines for suspected cancer. NICE clinical guideline 27 (2005). Available from www.nice.org.uk/guidance/CG27
- Leukapheresis for inflammatory bowel disease. NICE interventional procedure guidance 126 (2005). Available from www.nice.org.uk/guidance/IPG126
- Fertility. NICE clinical guidance 11 (2004). Available from www.nice.org.uk/guidance/CG11

NICE guidance under development

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

- Colorectal cancer. NICE clinical guideline. Publication expected October 2011
- Crohn's disease. NICE clinical guideline. Publication expected December 2012
- Adalimumab for second-line treatment of moderate to severe ulcerative colitis. NICE technology appraisal. Publication date to be confirmed.
- Patient experience in generic terms. NICE clinical guideline. Publication expected October 2011

7 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'
- 'Developing NICE quality standards: interim process guide'.

These are available from the NICE website

(www.nice.org.uk/GuidelinesManual and www.nice.org.uk/aboutnice/qualitystandards). Information on the progress of the guideline and quality standards is also available from the NICE website (www.nice.org.uk).