NICE National Institute for Health and Care Excellence

NICE guideline

Crohn's disease: management

Clinical guideline

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Contents

Introduction

Crohn's disease is a chronic inflammatory disease that mainly affects the gastrointestinal tract. There are currently at least 115,000 people in the UK with Crohn's disease. The causes of Crohn's disease are widely debated. Smoking and genetic predisposition are two important factors that are likely to play a role.

Typically people with Crohn's disease have recurrent attacks, with acute exacerbations interspersed with periods of remission or less active disease. Whether a relapse refers to a recurrence of symptoms or the appearance of mucosal abnormalities before the development of symptoms, remains the subject of dispute. Treatment is largely directed at symptom relief rather than cure, and active treatment of acute disease (inducing remission) should be distinguished from preventing relapse (maintaining remission).

Management options for Crohn's disease include drug therapy, attention to nutrition, smoking cessation and, in severe or chronic active disease, surgery.

The aims of drug treatment are to reduce symptoms and maintain or improve quality of life, while minimising toxicity related to drugs over both the short- and long-term. Glucocorticosteroid treatment, 5-aminosalicylate (5-ASA) treatment, antibiotics, immunosuppressives and tumour necrosis factor (TNF) alfa inhibitors are currently considered to be options for treating Crohn's disease. Enteral nutrition has also been used widely as first-line therapy in children and young people to facilitate growth and development, but its use in adults is less common. Between 50 and 80% of people with Crohn's disease will eventually need surgery for strictures causing symptoms of obstruction, other complications such as fistula formation, perforation or failure of medical therapy.

Considerations specific to children and young people

Up to a third of patients with Crohn's disease are diagnosed before the age of 21 but there is a lack of studies on treatment for children and young people. Paediatric practice is often based on extrapolation from adult studies and in this guideline all recommendations relate to adults, children and young people unless otherwise specified. Inducing and maintaining remission as well as optimising nutritional status and growth, and minimising psychological concerns and possible side effects of treatment are fundamental to best practice for all people with Crohn's disease, whatever their age.

Use of drugs

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients. Because the guidance covers children, but the summaries of product characteristics for many drugs do not include children, the guideline will assume that prescribers will consult the current online version of the British national formulary for children.

This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC's Good practice in prescribing medicines – guidance for doctors for further information. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations.

Patient-centred care

This guideline offers best practice advice on the care of adults, children and young people with Crohn's disease.

Treatment and care should take into account patients' needs and preferences. People with Crohn's disease should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health's advice on consent and the code of practice that accompanies the Mental Capacity Act. In Wales, healthcare professionals should follow advice on consent from the Welsh Government.

If the patient is under 16, healthcare professionals should follow the guidelines in the Department of Health's Seeking consent: working with children.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient's needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English.

Families and carers should also be given the information and support they need.

Care of young people in transition between paediatric and adult services should be planned and managed according to the best practice guidance described in the Department of Health's Transition: getting it right for young people.

Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people with Crohn's disease. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

- Ensure that information and advice about Crohn's disease:
    - is age appropriate
    - is of the appropriate cognitive and literacy level, and
    - meets the cultural and linguistic needs of the local community.
- Discuss treatment options and monitoring with the person with Crohn's disease, and/or their parent or carer if appropriate, and within the multidisciplinary team. Apply the principles outlined in Patient experience in adult NHS services (NICE clinical guidance 138).
- Give people with Crohn's disease, and/or their parents or carers if appropriate, additional information on the following when appropriate:
    - possible delay of growth and puberty in children
    - diet and nutrition
    - fertility and sexual relationships
    - prognosis
    - side effects of their treatment
    - cancer risk
    - surgery
    - care of young people in transition between paediatric and adult services
    - contact details for support groups.
- Offer adults, children and young people, and/or their parents or carers, age-appropriate multidisciplinary support to deal with any concerns about the disease and its treatment, including concerns about body image, living with a chronic illness, and attending school and higher education.
- Assess thiopurine methyltransferase (TPMT) activity before offering azathioprine or mercaptopurine[1]. Do not offer azathioprine or mercaptopurine if TPMT activity is deficient

(very low or absent). Consider azathioprine or mercaptopurine at a lower dose if TPMT activity is below normal but not deficient (according to local laboratory reference values).

- Monitor the effects of azathioprine, mercaptopurine and methotrexate[2],[3] as advised in the current online version of the British national formulary (BNF)[4] or British national formulary for children (BNFC). Monitor for neutropenia in those taking azathioprine or mercaptopurine even if they have normal TPMT activity.

- Ensure that there are documented local safety monitoring policies and procedures (including audit) for adults, children and young people receiving treatment that needs monitoring. Nominate a member of staff to act on abnormal results and communicate with GPs and people with Crohn's disease and/or their parents or carers, if appropriate.

- Discuss with people with Crohn's disease, and/or their parents or carers if appropriate, options for managing their disease when they are in remission, including both no treatment and treatment. The discussion should include the risk of inflammatory exacerbations (with and without drug treatment) and the potential side effects of drug treatment. Record the person's views in their notes.

- Do not offer a conventional glucocorticosteroid or budesonide to maintain remission.

[1] Although use is common in UK clinical practice, at the time of publication (October 2012) azathioprine and mercaptopurine did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC's Good practice in prescribing medicines – guidance for doctors for further information.

[2] Although use is common in UK clinical practice, at the time of publication (October 2012) azathioprine, mercaptopurine and methotrexate did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC's Good practice in prescribing medicines – guidance for doctors for further information.

[3] Follow BNF/BNFC cautions on prescribing methotrexate.

[4] Advice on monitoring of immunosuppressives can be found in the current online version of BNF/BNFC. The gastroenterology chapter and other relevant sections should be consulted.

1 Guidance

The following guidance is based on the best available evidence. The full guideline gives details of the methods and the evidence used to develop the guidance.

All recommendations relate to adults, children and young people unless otherwise specified. In this guideline, the term 'adults' is used to describe people who are aged 18 years or older, and 'children' those who are aged 11 years or younger. 'Young people' describes those who are aged 12 to 17 years.

1.1 Patient information and support

1.1.1 Ensure that information and advice about Crohn's disease:

- is age appropriate
- is of the appropriate cognitive and literacy level, and
- meets the cultural and linguistic needs of the local community.

1.1.2 Discuss treatment options and monitoring with the person with Crohn's disease, and/or their parent or carer if appropriate, and within the multidisciplinary team. Apply the principles outlined in Patient experience in adult NHS services (NICE clinical guidance 138).

1.1.3 Discuss the possible nature, frequency and severity of side effects of drug treatment[5] with people with Crohn's disease, and/or their parents or carers if appropriate.

1.1.4 Give all people with Crohn's disease, and/or their parents or carers if appropriate, information, advice and support in line with published NICE guidance on:

- smoking cessation
- patient experience
- medicines adherence
- fertility.

See Related NICE guidance.

1.1.5 Give people with Crohn's disease, and/or their parents or carers if appropriate, additional information on the following when appropriate:

- possible delay of growth and puberty in children and young people
- diet and nutrition
- fertility and sexual relationships
- prognosis
- side effects of their treatment
- cancer risk
- surgery
- care of young people in transition between paediatric and adult services
- contact details for support groups.

1.1.6 Offer adults, children and young people, and/or their parents or carers, age-appropriate multidisciplinary support to deal with any concerns about the disease and its treatment, including concerns about body image, living with a chronic illness, and attending school and higher education.

1.2 Inducing remission in Crohn's disease

Monotherapy

1.2.1 Offer monotherapy with a conventional glucocorticosteroid (prednisolone, methylprednisolone or intravenous hydrocortisone) to induce remission in people with a first presentation or a single inflammatory exacerbation of Crohn's disease in a 12-month period.

1.2.2 Consider enteral nutrition as an alternative to a conventional glucocorticosteroid to induce remission for:

- children in whom there is concern about growth or side effects, and

- young people in whom there is concern about growth.

1.2.3 In people with one or more of distal ileal, ileocaecal or right-sided colonic disease[6] who decline, cannot tolerate or in whom a conventional glucocorticosteroid is contraindicated, consider budesonide[7] for a first presentation or a single inflammatory exacerbation in a 12-month period. Explain that budesonide is less effective than a conventional glucocorticosteroid but may have fewer side effects.

1.2.4 In people who decline, cannot tolerate or in whom glucocorticosteroid treatment is contraindicated, consider 5-aminosalicylate (5-ASA) treatment[8] for a first presentation or a single inflammatory exacerbation in a 12-month period. Explain that 5-ASA is less effective than a conventional glucocorticosteroid or budesonide but may have fewer side effects than a conventional glucocorticosteroid.

1.2.5 Do not offer budesonide or 5-ASA treatment for severe presentations or exacerbations.

1.2.6 Do not offer azathioprine, mercaptopurine or methotrexate as monotherapy to induce remission.

Add-on treatment

1.2.7 Consider adding azathioprine or mercaptopurine[9] to a conventional glucocorticosteroid or budesonide[7] to induce remission of Crohn's disease if:

- there are two or more inflammatory exacerbations in a 12-month period, or
- the glucocorticosteroid dose cannot be tapered.

1.2.8 Assess thiopurine methyltransferase (TPMT) activity before offering azathioprine or mercaptopurine[9]. Do not offer azathioprine or mercaptopurine if TPMT activity is deficient (very low or absent). Consider azathioprine or mercaptopurine at a lower dose if TPMT activity is below normal but not deficient (according to local laboratory reference values).

1.2.9 Consider adding methotrexate[10],[11] to a conventional glucocorticosteroid or budesonide[7] to induce remission in people who cannot tolerate azathioprine or mercaptopurine, or in whom TPMT activity is deficient, if:

- there are two or more inflammatory exacerbations in a 12-month period, or
- the glucocorticosteroid dose cannot be tapered.

1.2.10 Monitor the effects of azathioprine, mercaptopurine[9] and methotrexate[10],[11] as advised in the current online version of the British national formulary (BNF)[12] or British national formulary for children (BNFC). Monitor for neutropenia in those taking azathioprine or mercaptopurine even if they have normal TPMT activity.

1.2.11 Ensure that there are documented local safety monitoring policies and procedures (including audit) for adults, children and young people receiving treatment that needs monitoring. Nominate a member of staff to act on abnormal results and communicate with GPs and people with Crohn's disease and/or their parents or carers, if appropriate.

Infliximab and adalimumab

The recommendations in the following section are from Infliximab and adalimumab for the treatment of Crohn's disease (NICE technology appraisal guidance 187).

1.2.12 Infliximab and adalimumab, within their licensed indications, are recommended as treatment options for adults with severe active Crohn's disease (see 1.2.17) whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Infliximab or adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed (see 1.2.15) to determine whether ongoing treatment is still clinically appropriate.

1.2.13 Treatment as described in 1.2.12 should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose). This may need to be varied for individual patients because of differences in the method of administration and treatment schedules.

1.2.14 Infliximab, within its licensed indication, is recommended as a treatment option for people with active fistulising Crohn's disease whose disease has not responded to conventional therapy (including antibiotics, drainage and immunosuppressive treatments), or who are intolerant of or have contraindications to conventional therapy. Infliximab should be given as a planned course of treatment until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed (see 1.2.15) to determine whether ongoing treatment is still clinically appropriate.

1.2.15 Treatment with infliximab or adalimumab (see 1.2.12 and 1.2.14) should only be continued if there is clear evidence of ongoing active disease as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. Specialists should discuss the risks and benefits of continued treatment with patients and consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People who continue treatment with infliximab or adalimumab should have their disease reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. People whose disease relapses after treatment is stopped should have the option to start treatment again.

1.2.16 Infliximab, within its licensed indication, is recommended for the treatment of people aged 6–17 years with severe active Crohn's disease whose disease has not responded to conventional therapy (including corticosteroids, immunomodulators and primary nutrition therapy), or who are intolerant of or have contraindications to conventional therapy. The need to continue treatment should be reviewed at least every 12 months.

1.2.17 For the purposes of this guidance, severe active Crohn's disease is defined as very poor general health and one or more symptoms such as weight loss, fever, severe abdominal pain and usually frequent (3–4 or more) diarrhoeal stools daily. People with severe active Crohn's disease may or may not develop new fistulae or have extra-intestinal manifestations of the disease. This clinical definition normally, but not exclusively, corresponds to a Crohn's Disease Activity Index (CDAI) score of 300 or more, or a Harvey-Bradshaw score of 8 to 9 or above.

1.2.18 When using the CDAI and Harvey-Bradshaw Index, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the scores and make any adjustments they consider appropriate.

1.2.19 Treatment with infliximab or adalimumab should only be started and reviewed by clinicians with experience of TNF inhibitors and of managing Crohn's disease.

1.3 Maintaining remission in Crohn's disease

1.3.1 Discuss with people with Crohn's disease, and/or their parents or carers if appropriate, options for managing their disease when they are in remission, including both no treatment and treatment. The discussion should include the risk of inflammatory exacerbations (with and without drug treatment) and the potential side effects of drug treatment. Record the person's views in their notes.

1.3.2 Offer colonoscopic surveillance in line with Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas (NICE clinical guideline 118).

Follow-up during remission for those who choose not to receive maintenance treatment

1.3.3 When people choose not to receive maintenance treatment:

- discuss and agree with them, and/or their parents or carers if appropriate, plans for follow-up, including the frequency of follow-up and who they should see
- ensure they know which symptoms may suggest a relapse and should prompt a consultation with their healthcare professional (most frequently, unintended weight loss, abdominal pain, diarrhoea, general ill-health)
- ensure they know how to access the healthcare system if they experience a relapse
- discuss the importance of not smoking.

Maintenance treatment for those who choose this option

1.3.4 Offer azathioprine or mercaptopurine[9] as monotherapy to maintain remission when previously used with a conventional glucocorticosteroid or budesonide to induce remission.

1.3.5 Consider azathioprine or mercaptopurine[9] to maintain remission in people who have not previously received these drugs (particularly those with adverse prognostic factors such as early age of onset, perianal disease, glucocorticosteroid use at presentation and severe presentations).

1.3.6 Consider methotrexate[10],[11] to maintain remission only in people who:

- needed methotrexate to induce remission, or
- have tried but did not tolerate azathioprine or mercaptopurine for maintenance or
- have contraindications to azathioprine or mercaptopurine (for example, deficient TPMT activity or previous episodes of pancreatitis).

1.3.7 Do not offer a conventional glucocorticosteroid or budesonide to maintain remission.

See recommendations 1.2.10 and 1.2.11 for guidance on monitoring the effects of azathioprine, mercaptopurine and methotrexate.

See recommendation 1.2.15 for when to continue infliximab or adalimumab during remission.

1.4 Maintaining remission in Crohn's disease after surgery

1.4.1 Consider azathioprine or mercaptopurine[9] to maintain remission after surgery in people with adverse prognostic factors such as:

- more than one resection, or
- previously complicated or debilitating disease (for example, abscess, involvement of adjacent structures, fistulising or penetrating disease).

1.4.2 Consider 5-ASA treatment[8] to maintain remission after surgery.

1.4.3 Do not offer budesonide or enteral nutrition to maintain remission after surgery.

1.5 Surgery

Crohn's disease limited to the distal ileum

1.5.1 Consider surgery as an alternative to medical treatment early in the course of the disease for people whose disease is limited to the distal ileum, taking into account the following:

- benefits and risks of medical treatment and surgery
- risk of recurrence after surgery[13]
- individual preferences and any personal or cultural considerations.

Record the person's views in their notes.

1.5.2 Consider surgery early in the course of the disease or before or early in puberty for children and young people whose disease is limited to the distal ileum and who have:

- growth impairment despite optimal medical treatment and/or
- refractory disease.

Discuss treatment options within the multidisciplinary team and with the person's parent or carer and, if appropriate, the child or young person.

Managing strictures

1.5.3 Consider balloon dilation particularly in people with a single stricture that is short, straight and accessible by colonoscopy.

1.5.4 Discuss the benefits and risks of balloon dilation and surgical interventions for managing strictures[14] with:

- the person with Crohn's disease and/or their parent or carer if appropriate and
- a surgeon and

- a gastroenterologist.

1.5.5 Take into account the following factors when assessing options for managing a stricture:

- whether medical treatment has been optimised
- the number and extent of previous resections
- the rapidity of past recurrence (if appropriate)
- the potential for further resections
- the consequence of short bowel syndrome
- the person's preference, and how their lifestyle and cultural background might affect management.

1.5.6 Ensure that abdominal surgery is available for managing complications or failure of balloon dilation.

1.6 Monitoring for osteopenia and assessing fracture risk

Refer to the NICE clinical guideline on Osteoporosis: assessing the risk of fragility fracture (NICE clinical guideline 146) for recommendations on assessing the risk of fragility fracture in adults. Crohn's disease is a cause of secondary osteoporosis.

1.6.1 Do not routinely monitor for changes in bone mineral density in children and young people.

1.6.2 Consider monitoring for changes in bone mineral density in children and young people with risk factors, such as low body mass index (BMI), low trauma fracture or continued or repeated glucocorticosteroid use.

1.7 Conception and pregnancy

1.7.1 Give information about the possible effects of Crohn's disease on pregnancy, including the potential risks and benefits of medical treatment and the possible effects of Crohn's disease on fertility.

1.7.2 Ensure effective communication and information-sharing across specialties (for example, primary care, obstetrics and gastroenterology) in the care of pregnant women with Crohn's disease.

[5] Appendices L and M of the full guideline contain observational data on adverse events associated with 5-ASA treatment and immunosuppressives.

[6] See recommendations 1.5.1 and 1.5.2 for when to consider surgery early in the course of the disease for people whose disease is limited to the distal ileum.

[7] Although use is common in UK clinical practice, at the time of publication (October 2012), budesonide did not have a UK marketing authorisation specifically for children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information.

[8] Although use is common in UK clinical practice, at the time of publication (October 2012) mesalazine, olsalazine and balsalazide did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC's Good practice in prescribing medicines – guidance for doctors for further information.

[9] Although use is common in UK clinical practice, at the time of publication (October 2012) azathioprine and mercaptopurine did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC's Good practice in prescribing medicines – guidance for doctors for further information.

[10] Although use is common in UK clinical practice, at the time of publication (October 2012) methotrexate did not have UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC's Good practice in prescribing medicines – guidance for doctors for further information.

[11] Follow BNF/BNFC cautions on prescribing methotrexate.

[12] Advice on monitoring of immunosuppressives can be found in the BNF/BNFC. The gastroenterology chapter and other relevant sections should be consulted.

[13] Appendix N of the full guideline contains observational data on recurrence rates after surgery.

[14] Appendix O of the full guideline contains observational data on efficacy, safety, quality of life and time to recurrence for balloon dilation and surgery for stricture.

2 Notes on the scope of the guidance

NICE guidelines are developed in accordance with a scope that defines what the guideline will and will not cover.

How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see appendix A), which reviewed the evidence and developed the recommendations.

There is more information about how NICE clinical guidelines are developed on the NICE website. A booklet, How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS is available.

3 Implementation

NICE has developed tools to help organisations implement this guidance.

4 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

4.1 Azathioprine

For patients with intestinal Crohn's disease, does the addition of azathioprine to glucocorticosteroid treatment at diagnosis improve the long-term outcome compared with glucocorticosteroid treatment alone?

Why this is important

Crohn's disease runs a relapsing and remitting course, with a significant inflammatory component during its early stages, and increasing degrees of fibrotic, stenosing or perforating disease later. Intervention during the inflammatory stage may affect disease progression while avoiding the side effects of glucocorticosteroid treatment – the current mainstay of treatment for exacerbations. Adults and children with a first presentation of intestinal Crohn's disease would be recruited once in remission and randomised to receive azathioprine or placebo for preventing relapse after an initial treatment with a glucocorticosteroid. Co-primary end points would be quality of life measures and maintaining glucocorticosteroid-free remission measured by the Crohn's Disease Activity Index (CDAI). Secondary end points would be mucosal healing at endoscopy, hospitalisation, side effects and surgery. Appropriate healthcare costs would also need to be assessed to inform a cost-effectiveness model. Follow-up should be at least 2 years, and ideally 5 years.

4.2 Enteral nutrition

What are the benefits, risks and cost effectiveness of enteral nutrition compared with glucocorticosteroid treatment in adults and children?

Why this is important

Previous studies in adults suggest that glucocorticosteroid treatment is more effective at inducing remission than enteral nutrition in adults with Crohn's disease, but some small paediatric studies suggest that growth and mucosal healing may be better following treatment with enteral nutrition. In clinical practice enteral nutrition is often used to avoid the side effects of glucocorticosteroid treatment in children. There is little information about the relative effects on quality of life, bone

density or cost effectiveness. Randomised controlled trials should be conducted in children and adults with an inflammatory exacerbation of Crohn's disease to compare the effects of enteral nutrition and glucocorticosteroid treatment on these parameters and also the effect on growth in children. Mucosal healing could also be assessed in a subgroup of participants. It is not ethical or practical to conduct a randomised controlled trial of enteral nutrition versus placebo.

4.3 5-ASA treatment

Following successful medical induction of remission of Crohn's disease of the colon, is mesalazine more clinically and cost effective than no treatment?

Why this is important

The evidence for use of this group of drugs for maintenance of remission in Crohn's disease is not clear, and in particular, there is very limited reporting of disease site. It is therefore possible that this might be a cost-effective treatment for maintenance of remission, with limited toxicity. Its use in this setting may therefore be associated with higher rates of successful maintenance of disease remission, reduced need for escalation of therapy, higher quality of life, and lower rates of hospital admissions and surgeries. The question is applicable to adults, young people and children, and trials in all are therefore required. A conventional glucocorticosteroid would be offered to induce remission in a first presentation of colonic Crohn's disease. Patients would be recruited once in remission and glucocorticosteroid-free and randomised to receive mesalazine or placebo, for maintenance of remission. Co-primary end points would be quality of life measures and maintenance of glucocorticosteroid-free remission measured by the Crohn's Disease Activity Index (CDAI). Secondary end points would be mucosal healing at endoscopy, need for escalation of therapy to azathioprine or biological therapy, adverse events, hospitalisation and surgery. The time frame for follow-up should be at least 12 months, but ideally 24–36 months.

4.4 Surgery versus medical treatment for the distal ileum

What is the effect on quality of life of medical treatment (immunosuppressive or biological therapy) compared with early surgery for Crohn's disease limited to the distal ileum?

Why this is important

Patients first presenting with Crohn's disease limited to the distal ileum are usually treated medically. When relapse occurs there is the option of further medical treatment or surgery. Recurrence and reoperation rates are high after surgery, but most people with medically treated

Crohn's disease require surgery at some time. There are no comparative studies reporting the quality of life associated with and long-term outcome of these management strategies. A multicentre trial is currently in progress in Holland in which patients with Crohn's disease limited to the distal ileum are randomised to treatment with a biological agent or laparoscopic surgical resection at the point at which initial medical treatment fails. A similar trial should be carried out in the UK, also considering the effectiveness of azathioprine as a medical treatment option.

4.5 Patient information and support

What are the information needs of people with Crohn's disease, as defined by people with the condition, and can education and support based on these needs lead to better clinical and quality of life outcomes?

Why this is important

Crohn's disease is a life-long condition that continues to have a significant impact on all aspects of life. The development of an educational and support programme could substantially reduce the cost of treatment and the social impact of the disease. Further research should be undertaken to determine the information and support needs of people with Crohn's disease. It should use qualitative techniques to identify the concerns of people with the condition and how they should be best addressed. Delphi techniques would ensure that the professional understanding of these needs was appropriate. From this work a randomised controlled trial would be designed to investigate the impact of a patient-originated programme on health outcomes, including frequency of relapse and need for surgery as well as quality of life issues.

5 Other versions of this guideline

5.1 Full guideline

The full guideline, Crohn's disease: management in adults, children and young people contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre.

5.2 NICE pathway

The recommendations from this guideline have been incorporated into a NICE pathway.

5.3 'Information for the public'

A summary of the recommendations is available for the public ('Information for the public'').

We encourage NHS and voluntary sector organisations to use this text in their own information about Crohn's disease.

6 Related NICE guidance

6.1 *Incorporated guidance*

This guideline incorporates the following NICE guidance:

- Infliximab (review) and adalimumab for the treatment of Crohn's disease. NICE technology appraisal guidance 187 (2010).

6.2 *Other related NICE guidance*

Published

- Osteoporosis: assessing the risk of fragility fracture. NICE clinical guideline 146 (2012).
- Patient experience in adult NHS services. NICE clinical guidance 138 (2012).
- Colorectal cancer: the diagnosis and management of colorectal cancer. NICE clinical guideline 131 (2011).
- Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas. NICE clinical guideline 118 (2011).
- Extracorporeal photopheresis for Crohn's disease. NICE interventional procedure guidance 288 (2009).
- Medicines adherence. NICE clinical guideline 76 (2009).
- Irritable bowel syndrome in adults. NICE clinical guideline 61 (2008).
- Smoking cessation services. NICE public health guidance 10 (2008).
- Faecal incontinence: the management of faecal incontinence in adults. NICE clinical guideline 49 (2007).
- Varenicline for smoking cessation. NICE technology appraisal guidance 123 (2007).
- Brief interventions and referral for smoking cessation. NICE public health guidance 1 (2006).
- Nutrition support in adults. NICE clinical guideline 32 (2006).
- Leukapheresis for inflammatory bowel disease. NICE interventional procedure guidance 126 (2005).

- Dyspepsia: managing dyspepsia in primary care. NICE clinical guideline 17 (2004).
- Fertility. NICE clinical guideline 11 (2004).
- Wireless capsule endoscopy for investigation of the small bowel. NICE interventional procedure guidance 101 (2004).

7 Updating the guideline

NICE clinical guidelines are updated so that recommendations take into account important new information. New evidence is checked after publication, and healthcare professionals and patients are asked for their views; we use this information to decide whether all or part of a guideline needs updating. If important new evidence is published at other times, we may decide to do a more rapid update of some recommendations. Please see our website for information about updating the guideline.

Appendix A: The Guideline Development Group, National Collaborating Centre and NICE project team

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About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

The guideline was developed by the National Clinical Guideline Centre, which is based at the Royal College of Physicians. The Centre worked with a group of healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, who reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in The guidelines manual.

The recommendations from this guideline have been incorporated into a NICE Pathway. We have produced information for the public. Tools to help you put the guideline into practice and information about the evidence it is based on are also available.

Your responsibility

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, 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, and informed by the summary of product characteristics of any drugs they are considering.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

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