Coeliac disease: recognition, assessment and management of coeliac disease

NICE guideline

Draft for consultation, March, 2015

If you wish to comment on this version of the guideline, please be aware that all the supporting information and evidence is contained in the full version.

Contents

Introduction

Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients. Dietary proteins, known as glutens, which are present in wheat, barley and rye activate an abnormal mucosal immune response. Clinical and histological improvements usually follow when gluten is excluded from the diet.

Coeliac disease can present with a wide range of clinical features, both gastrointestinal (such as indigestion, diarrhoea, abdominal pain, bloating, distension or constipation) and non-gastrointestinal (such as fatigue, dermatitis herpetiformis, iron deficiency, anaemia, osteoporosis, reproductive problems, short stature, neuropathy, ataxia or delayed puberty). Although some people present with typical symptoms, others will initially experience few or no symptoms.

Coeliac disease is a common condition. Population screening studies suggest that in the UK 1 in 100 people are affected. The complications of coeliac disease (which may or may not be present at diagnosis) can include osteoporosis, ulcerative jejunitis, malignancy (intestinal lymphoma), functional hyposplenism, vitamin D deficiency and iron deficiency.

People with a number of conditions such as type 1 diabetes, autoimmune thyroid disease, and irritable bowel syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having coeliac disease.

The treatment of coeliac disease is a lifelong gluten-free diet. Specific education and information, such as advice and education on alternative foods in the diet to maintain a healthy and varied intake, may increase the likelihood of adherence and a positive prognosis. These could be provided by a dietitian with experience in coeliac disease. However access to specialist dietetic support is currently poor within the UK.

Safeguarding children

Remember that child maltreatment:

- is common
- can present anywhere
- may co-exist with other health problems, including coeliac disease.

See the NICE guideline on child maltreatment for clinical features that may be associated with maltreatment.

Medicines

The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Patient-centred care

This guideline offers best practice advice on the care of children, young people and adults (18 years and over) with suspected or confirmed coeliac disease. For the purposes of this guideline populations have been defined in the following way; children are those under the age of 13, young people are those aged between 13 and 17 years, and adults are those aged 18 and above.

Patients and healthcare professionals have rights and responsibilities as set out in the NHS Constitution for England – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. If it is clear that the child or young person fully understands the treatment and does not want their family or carers to be involved, they can give their own consent. Healthcare professionals should follow the Department of Health's advice on consent. If someone does not have capacity to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act and the supplementary code of practice on deprivation of liberty safeguards.

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in Patient experience in adult NHS services.

If a young person is moving between paediatric and adult services, care 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 coeliac 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.

Strength of recommendations

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also 'Patient-centred care').

Interventions that must (or must not) be used

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

Interventions that should (or should not) be used – a 'strong' recommendation

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer…') when we are confident that an intervention will not be of benefit for most patients.

Interventions that could be used

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values

and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

Update information

This guidance is an update of NICE clinical guideline 86 (published May 2009) and will replace it.

The original NICE guideline and supporting documents are available here.

Key priorities for implementation

The following recommendations have been identified as priorities for implementation. The full list of recommendations is in section 1.

- Offer serological testing for coeliac disease to people with any of the following:
  - persistent unexplained abdominal or gastrointestinal symptoms
  - faltering growth
  - prolonged fatigue
  - unexpected weight loss
  - severe or persistent mouth ulcers
  - unexplained iron, vitamin B12 or folate deficiency
  - first-degree relatives of people with coeliac disease
  - people with type 1 diabetes, at diagnosis
  - people with auto immune thyroid disease, at diagnosis
  - adults with irritable bowel syndrome. **[1.1.1]**
- When healthcare professionals request serological tests to investigate suspected coeliac disease in young people and adults, laboratories should:
  - test for total immunoglobulin A (IgA) and IgA tissue transglutaminase (tTG) as the first choice
  - use IgA endomysial antibodies (EMA) if IgA tTG is weakly positive
  - consider using IgG EMA, IgG deaminated gliadin peptide (DGP) or IgG tTG If IgA is deficient. **[1.2.2]**
- When healthcare professionals request serological tests to investigate suspected coeliac disease in children, laboratories should:
  - test for total IgA, IgA tTG, and IgA EMA as the first choice
  - consider using IgG EMA, IgG DGP or IgG tTG if IgA is deficient. **[1.2.3]**
- Offer access to specialist dietetic and nutritional advice as part of an annual review. During the review:
  - assess diet and adherence to the gluten-free diet
  - measure weight and height
  - review symptoms. **[1.4.3]**

- Consider the following in people with coeliac disease who have persistent symptoms despite advice to exclude gluten from their diet:
  - Review the certainty of the original diagnosis.
  - Refer to a specialist dietitian to investigate continued exposure to gluten.
  - Investigate potential complications or coexisting conditions that may be causing persistent symptoms, such as irritable bowel syndrome, lactose intolerance, bacterial overgrowth, microscopic colitis or inflammatory colitis. **[1.5.1]**
- For people undergoing investigations for coeliac disease:
  - Explain that any test is accurate only if a gluten-containing diet is eaten during the diagnostic process.
  - Advise not to start a gluten-free diet until diagnosis is confirmed by a specialist, even if the results of a serological test are positive. **[1.6.1]**
- A healthcare professional with a specialist knowledge of coeliac disease should tell people with the disease (and their family members or carers where appropriate) about the importance of a gluten-free diet and give them information to help them follow it. This should include:
  - information on which types of food contain gluten
  - explanations of food labelling
  - information sources about gluten-free diets, recipe ideas and cookbooks
  - how to manage social situations, eating out and travelling away from home, including travel abroad
  - avoiding cross contamination in the home and minimising the risk of accidental gluten intake when eating out
  - the role of local support groups . **[1.6.6]**

1 Recommendations

The following guidance is based on the best available evidence. The full guideline [hyperlink to be added for final publication] gives details of the methods and the evidence used to develop the guidance.

1.1 Recognition of coeliac disease

1.1.1 Offer serological testing for coeliac disease to people with any of the following:

- persistent unexplained abdominal or gastrointestinal symptoms
- faltering growth
- prolonged fatigue
- unexpected weight loss
- severe or persistent mouth ulcers
- unexplained iron, vitamin B12 or folate deficiency
- first-degree relatives of people with coeliac disease
- people with type 1 diabetes, at diagnosis
- people with auto immune thyroid disease, at diagnosis
- adults with irritable bowel syndrome.

1.1.2 Consider serological testing for coeliac disease in people with any of the following:

- metabolic bone disorder (reduced bone mineral density or osteomalacia)
- unexplained neurological symptoms (particularly peripheral neuropathy or ataxia)
- unexplained subfertility or recurrent miscarriage
- persistently raised liver enzymes with unknown cause
- dental enamel defects
- Down's syndrome
- Turner syndrome.

1.1.3 Advise people who have tested negative for coeliac disease, particularly first-degree relatives and people with type 1 diabetes, that they may need re-testing if they become symptomatic.

1.2 Serological testing for coeliac disease

1.2.1 All serological tests should be undertaken in laboratories with clinical pathology accreditation (CPA) or ISO15189 accreditation.

1.2.2 When healthcare professionals request serological tests to investigate suspected coeliac disease in young people and adults, laboratories should:

- test for total immunoglobulin A (IgA) and IgA tissue transglutaminase (tTG) as the first choice
- use IgA endomysial antibodies (EMA) if IgA tTG is weakly positive
- consider using IgG EMA, IgG deaminated gliadin peptide (DGP) or IgG tTG if IgA is deficient.

1.2.3 When healthcare professionals request serological tests to investigate suspected coeliac disease in children, laboratories should:

- test for total IgA, IgA tTG, and IgA EMA as the first choice
- consider using IgG EMA, IgG DGP or IgG tTG if IgA is deficient.

1.2.4 Do not offer serological testing for coeliac disease in infants before gluten has been introduced into the diet.

1.2.5 When laboratories test for total IgA, a specific assay designed to measure total IgA levels should be used.

1.2.6 Do not use human leukocyte antigen (HLA) DQ2/DQ8 testing in the initial diagnosis of coeliac disease in non-specialist settings.

1.2.7 Consider using HLA DQ2/DQ8 testing in the diagnosis of coeliac disease in specialist settings (for example, in children who are not

having a biopsy, or in people who already have limited gluten ingestion and choose not to have a gluten challenge).

1.2.8 Laboratories should clearly communicate the interpretation of serological test results and recommended action to healthcare professionals.

1.3 Referral of people with suspected coeliac disease

1.3.1 Refer young people and adults with positive serological test results[1] to a gastrointestinal specialist for endoscopic intestinal biopsy to confirm or exclude coeliac disease.

1.3.2 Refer children with positive serological test results[2] to a paediatrician with a specialist interest in gastroenterology for further investigation for coeliac disease.

1.3.3 Refer people with negative serological test results to a gastrointestinal specialist for further assessment if coeliac disease is still clinically suspected.

1.4 Monitoring in people with coeliac disease

1.4.1 Consider referring people with coeliac disease for endoscopic intestinal biopsy if continued exposure to gluten has been excluded and:

- serological titres are persistently high and show little or no change after 12 months **or**
- they have persistent symptoms, including diarrhoea, abdominal pain, weight loss, lethargy or unexplained anaemia.

[1] In young people and adults, a positive serological test result is defined as: strongly positive IgA tTG alone, **or** weakly positive IgA tTG **and** a positive IgA EMA test result. Note: In those who have IgA deficiency, a serologically positive result can be derived from any one of the IgG antibodies.

[2] In children, a positive serological test result is defined as: a positive IgA tTG **and/or** a positive IgA EMA test result. Note: In those who have IgA deficiency, a serologically positive result can be derived from any one of the IgG antibodies.

1.4.2 Do not use serological testing alone to determine whether gluten has been excluded from the person's diet.

1.4.3 Offer access to specialist dietetic and nutritional advice as part of an annual review. During the review:

- assess diet and adherence to the gluten-free diet
- measure weight and height
- review symptoms.

1.4.4 Refer to a medical professional if concerns are raised in the annual review. The medical professional should:

- assess the need for a DEXA (dual-energy X-ray absorptiometry) scan or active treatment of bone disease
- assess the need for specific blood tests
- assess the risk of long-term complications and comorbidities
- assess the need for specialist referral.

1.5 Non-responsive and refractory coeliac disease

1.5.1 Consider the following in people with coeliac disease who have persistent symptoms despite advice to exclude gluten from their diet:

- Review the certainty of the original diagnosis.
- Refer to a specialist dietitian to investigate continued exposure to gluten.
- Investigate potential complications or coexisting conditions that may be causing persistent symptoms, such as irritable bowel syndrome, lactose intolerance, bacterial overgrowth, microscopic colitis or inflammatory colitis.

1.5.2 Diagnose refractory coeliac disease if the original diagnosis of coeliac disease has been confirmed, and exposure to gluten and any coexisting conditions have been excluded as the cause of continuing symptoms.

1.5.3 Refer people with refractory coeliac disease to a specialist centre for further investigation.

1.5.4 Consider prednisolone or prednisone for the initial management of the symptoms of refractory coeliac disease while waiting for specialist advice.

1.6 Information and support

1.6.1 For people undergoing investigations for coeliac disease:

- Explain that any test is accurate only if a gluten-containing diet is eaten during the diagnostic process.
- Advise not to start a gluten-free diet until diagnosis is confirmed by a specialist, even if the results of a serological test are positive.

1.6.2 Advise people who are following a normal diet (containing gluten) to eat some gluten in more than 1 meal every day for at least 6 weeks before testing.

1.6.3 If people who have restricted their gluten intake or excluded gluten from their diet are reluctant or unable to re-introduce gluten into their diet before testing:

- refer to a gastrointestinal specialist and
- explain that it may be difficult to confirm their diagnosis by intestinal biopsy.

1.6.4 Explain to people who are thought to be at risk of coeliac disease that a delayed diagnosis, or undiagnosed coeliac disease, can result in continuing ill health and serious long-term complications.

1.6.5 Give people with coeliac disease (and their family members or carers where appropriate) useful sources of information on the disease, including national and local coeliac specialist groups and dietitians with a specialist knowledge in coeliac disease.

1.6.6 A healthcare professional with a specialist knowledge of coeliac disease should tell people with the disease (and their family members or carers where appropriate) about the importance of a gluten-free diet and give them information to help them follow it. This should include:

- information on which types of food contain gluten
- explanations of food labelling
- information sources about gluten-free diets, recipe ideas and cookbooks
- how to manage social situations, eating out and travelling away from home, including travel abroad
- avoiding cross contamination in the home and minimising the risk of accidental gluten intake when eating out
- the role of local support groups.

1.6.7 Be aware that people with coeliac disease may experience anxiety and depression. Diagnose and manage these issues in accordance with the following NICE guidelines:

- Depression in adults with a chronic physical health problem
- Depression in children and young people
- Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults.
- Social anxiety disorder

1.7 Advice on dietary management

1.7.1 Advise people with coeliac disease (and their family members or carers where appropriate) to talk to a member of their healthcare team if they are thinking about taking over-the-counter vitamin or mineral supplements.

1.7.2 Explain to people with coeliac disease (and their family members or carers where appropriate) that they may need to take specific

supplements such as calcium or vitamin D if their dietary intake is insufficient.

1.7.3 Explain to people with coeliac disease (and their family members or carers where appropriate) that:

- they can choose to include gluten-free oats in their diet at any stage and
- they will be advised whether to continue eating gluten-free oats depending on their immunological, clinical or histological response.

2 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. The Guideline Development Group's full set of research recommendations is detailed in the full guideline.[hyperlink to be added for final publication]

2.1 Serological testing in people who have IgA deficiency

What is the sensitivity and specificity of IgG tTG, IgG EMA and IgG DGP tests in detecting coeliac disease in people with IgA deficiency?

Why this is important

IgA deficiency is significantly more common in people with coeliac disease than in the general population. People with IgA deficiency will have a false negative result when tested for IgA antibody, which may lead to a missed diagnosis of coeliac disease. A missed diagnosis may in turn result in increased use of NHS resources and the person experiencing the risks associated with undiagnosed coeliac disease. IgG antibodies are recommended for use in place of IgA antibodies in people who have IgA deficiency, but there is limited evidence to demonstrate the sensitivity and specificity of tests for IgG antibodies – that is, IgG tTG, IgG EMA and IgG DGP – in people suspected of having coeliac disease with IgA deficiency.

2.2 Serological testing in people who test negative for anti-transglutaminase

What is the sensitivity and specificity of IgA EMA and IgA DGP tests in detecting coeliac disease in people who test negative for IgA tTG?

Why this is important

In people with suspected coeliac disease, IgA tTG is most commonly used as the first-choice test to detect the presence of coeliac disease antibodies. IgA tTG does not have perfect sensitivity and specificity, therefore some people with coeliac disease will get a false negative result. If this happens, and if there is a strong and ongoing clinical suspicion of coeliac disease, serological testing for IgA EMA or IgA or IgG DGP antibodies should also be requested. However, it is important to note that there is little evidence for the sensitivity and specificity of these antibodies in people who have tested negative for IgA tTG antibodies. A clearer understanding of the sensitivity and specificity of EMA and DGP antibodies in people who have tested negative for IgA tTG will allow clinicians to better interpret test results and make a more informed diagnosis.

2.3 Dietary supplements

Should people with coeliac disease be offered calcium and vitamin D supplements for a specific time period soon after their initial diagnosis?

Why this is important

People with coeliac disease are at an increased risk of malabsorption of key nutrients such as calcium and vitamin D. This is because of the role gluten plays in preventing these nutrients from being properly absorbed. It is not known how long the body takes to properly absorb these vitamins and minerals once a gluten-free diet is started. It is also not known whether the majority of people diagnosed with coeliac disease have enough calcium and vitamin D in their diet, or whether some people with coeliac disease are able to get enough of these nutrients from what they eat. Answering this research question will help healthcare professionals to understand whether calcium and

vitamin D should be offered to everyone at the time of diagnosis and for how long these vitamin and mineral supplements should be taken.

2.4 Dietitian contribution to patient management

How can the role of the dietitian contribute most effectively within a coeliac disease team?

Why this is important

As a gluten-free diet is the primary treatment option for people with coeliac disease, it is important that a dietitian with a specialist interest in coeliac disease should play a significant role in their care and follow up. Many of the common problems associated with the long-term management of coeliac disease happen because of non-adherence to a gluten-free diet. It is important to explore how to maximise the effectiveness of the dietitian role in helping people with coeliac disease to adhere to a gluten-free diet.

2.5 Frequency of monitoring

What is the effectiveness of more frequent monitoring compared with monitoring at 12 months after diagnosis in people with newly diagnosed coeliac disease?

Why this is important

It is currently not known how often people with coeliac disease should have their condition monitored. No research has adequately investigated the effectiveness of different monitoring frequencies. There is variation across the UK in how often people with coeliac disease have their condition monitored. Further research within this area is important to ensure that people with coeliac disease are having their condition adequately monitored.

3 Other information

3.1 Scope and how this guideline was developed

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 Internal Clinical Guidelines Programme to develop this guideline. The Centre established a Guideline Development Group (see section 4), which reviewed the evidence and developed the recommendations.

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

3.2 Related NICE guidance

Details are correct at the time of consultation on the guideline (March 2015). Further information is available on the NICE website.

General

- Patient experience in adult NHS services (2012) NICE guideline CG138

Condition-specific

- Colorectal cancer (2014) NICE guideline CG131
- Faecal calprotectin diagnostic tests for inflammatory diseases of the bowel (2013) NICE diagnostics guidance DG11
- Fertility (2013) NICE guideline CG156
- Crohn's disease (2012) NICE guideline CG152
- Osteoporosis (2012) NICE guideline CG146
- Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas (2011) NICE guideline CG118
- Food allergy in children and young people (2011) NICE guideline CG116
- Constipation in children and young people (2010) NICE guideline CG99
- Rheumatoid arthritis (2009) NICE guideline CG79
- Irritable bowel syndrome in adults (2015) NICE guideline CG61

- Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy) (2007) NICE guideline CG53
- Nutrition support in adults (2006) NICE guideline CG32
- Type 1 diabetes (2004) NICE guideline CG15

Under development

NICE is developing the following guidance:

- Type 1 diabetes NICE guideline. Publication expected August 2015
- Diabetes in children and young people. NICE guideline. Publication expected August 2015

4 The Guideline Development Group, National Collaborating Centre and NICE project team, and declarations of interests

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4.4 Declarations of interests

The following members of the Guideline Development Group made declarations of interests. All other members of the Group stated that they had no interests to declare.

Member	Interest declared	Type of interest	Decision taken
Sorrel Burden	Systematic reviewer on a project run by NPS Pharma UK Ltd - 'Investigating the Burden of disease and Quality of Life of patients on long term parenteral nutrition'. A fee for the work was paid to SB's employer, Manchester University. NHS Pharma do not make products licensed for use in Coeliac.	Non-specific, non-personal pecuniary	Declare and participate
Martin Dadswell	Invited to join the Citizens Board for Southwark and Lambeth Integrated Care.	Non-specific, non-personal pecuniary	Declare and participate
Peter Gillett	Work carried out with University of Birmingham (Sponsored by Warburtons). Created DVD of patient and HC professionals attitudes to Coeliac Disease. Travel expenses paid by University.	Specific, non-personal pecuniary	Declare and participate
Anne Holdoway	Chaired a Dr Schar study day on nutrition in November 2013. Travel and subsistence paid. Honorarium donated in full to charity.	Specific, non-personal pecuniary	Declare and participate
Norma McGough	Research conference in March 2014 - run by Coeliac UK - funded by a variety of sponsors - for example Warburtons, Thermo-Fischer, Glutafin and Juvela. Sponsors do not have any input to the conference.	Specific, non-personal pecuniary	Declare and participate
Simon Murch	Received a consultancy fee in 2012 from Mead Johnson, a manufacturer of hypoallergenic formulae (not CD related). Lectured on this topic in 2012 and received an honorarium.	Non-specific, personal pecuniary interest	Declare and participate
Simon Murch	Member of ESPGHAN, which published new diagnostic guidelines in 2012.	Non-specific, personal pecuniary interest	Declare and participate
Simon Murch	Council Member of BSPGHAN. Appointed Chair of the BSPGHAN Coeliac Disease Working Group in 2011.	Non-specific, personal pecuniary interest	Declare and participate
Simon Murch	Author on a paper discussing Matrix Expansion and Syncytial Aggregation of Syndecan-1+ Cells Underpin Villous Atrophy in	Non-specific, personal pecuniary interest	Declare and participate

	Coeliac Disease.		
Gerry Robins	Travel and subsistence for attendance to Dr Falk GI symposium. Dr Falk do not make products licensed for use in Coeliac.	Non-specific, non-personal pecuniary interest	Declare and participate
David Sanders	Awarded grant in 2011 from Dr Schar to undertaking work on gluten sensitive IBS.	Non-specific, personal pecuniary interest	Declare and participate
David Sanders	Principle Investigator (2011 - 2013) for Dr Schar on IBS research.	Non-specific, personal pecuniary interest	Declare and participate
David Sanders	Principle Investigator (2011 - 2013) for Simtomax - manufacturers of point of care tests.	Non-specific, personal pecuniary interest	Declare and participate
David Sanders	Chair of the Coeliac UK Health Advisory Council.	Specific, non-personal pecuniary	Declare and participate
Jeremy Woodward	Received a £500 honorarium from Tillotts Pharma in 2012 for participation in an Advisory Board discussion about point of care diagnostic tests in Coeliac Disease.	Non-specific, personal pecuniary interest	Declare and participate