# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health and social care directorate

## Quality standards and indicators

## Briefing paper

**Quality standard topic:** Coeliac disease

**Output:** Prioritised quality improvement areas for development.

**Date of Quality Standards Advisory Committee meeting:** 16 December 2015

## Contents

# 1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for coeliac disease. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

## *1.1 Structure*

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

## *1.2 Development source*

The key development source referenced in this briefing paper is:

Coeliac disease: recognition, assessment and management. NICE guideline NG20 (2015)

This guideline updated and replaced CG86. No review schedule presented.

# 2 Overview[1]

## *2.1 Focus of quality standard*

This quality standard will cover the recognition, assessment and management of coeliac disease in children, young people and adults.

## *2.2 Definition*

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,

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[1] Unless otherwise referenced, sections 2.2 to 2.4 are adapted from NICE guideline NG20 Coeliac disease (2015)

anaemia, osteoporosis, reproductive problems, neuropathy, ataxia or delayed puberty). Children may also present with features such as faltering growth, static weight or progressive weight loss. Although some people present with typical symptoms, others will initially experience few or no symptoms.

## *2.3 Incidence and prevalence*

Coeliac disease is a common condition. Population screening studies suggest that in the UK 1 in 100 people are affected, giving a prevalence of around 530,000 in England. 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 conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner 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.

## *2.4 Management*

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 patchy in the UK.

The majority of people with coeliac disease report a rapid clinical improvement after starting a gluten-free diet. Some people do not report symptomatic improvement after starting treatment, and some will still have persisting symptoms after 6 to 12 months. Approximately 10% of people with non-responsive coeliac disease will have true refractory coeliac disease. The management of people with refractory coeliac disease currently varies widely within the UK.

People with coeliac disease are at risk of complications and may have other coexisting conditions. The follow-up care of people with coeliac disease after the diagnosis varies widely within the UK ranging from follow-up care in specialist clinics to being discharged back to the community without any provision of a follow-up service.

## *2.5 National Outcome Frameworks*

Tables 1 and 2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

**Table 1** NHS Outcomes Framework 2015–16

| **Domain** | **Overarching indicators and improvement areas** |
|---|---|
| 1 Preventing people from dying prematurely | ***Overarching indicators***<br>1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare<br>i Adults<br>***Improvement areas***<br>**Reducing premature mortality from the major causes of death**<br>1.4 Under 75 mortality rate from cancer* |
| 2 Enhancing quality of life for people with long-term conditions | ***Overarching indicator***<br>2 Health-related quality of life for people with long-term conditions**<br>***Improvement areas***<br>**Ensuring people feel supported to manage their condition**<br>2.1 Proportion of people feeling supported to manage their condition |
| 4 Ensuring that people have a positive experience of care | ***Overarching indicators***<br>4a Patient experience of primary care<br>i GP services<br>*4d Patient experience characterised as poor or worse*<br>*I Primary care*<br>***Improvement areas***<br>**Improving people's experience of outpatient care**<br>4.1 Patient experience of outpatient services<br>**Improving people's experience of integrated care**<br>*4.9 People's experience of integrated care*** |
| **Alignment with Adult Social Care Outcomes Framework and/or Public Health Outcomes Framework**<br>* Indicator is shared<br>** Indicator is complementary<br>Indicators in italics in development | |

**Table 2** Public health outcomes framework for England, 2013–2016

| **Domain** | **Objectives and indicators** |
|---|---|
| 4 Healthcare public health and preventing premature mortality | ***Objective***<br>Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities<br>***Indicators***<br>4.3 Mortality rate from causes considered preventable**<br>4.5 Under 75 mortality rate from cancer*<br>4.13 Health-related quality of life for older people<br>4.14Hip fractures in people aged 65 and over |
| ***Alignment with Adult Social Care Outcomes Framework and/or NHS Outcomes Framework***<br>* Indicator is shared<br>** Indicator is complementary | |

# 3 Summary of suggestions

## 3.1 Responses

In total, 11 stakeholders responded to the 2-week engagement exercise 22/10/15 – 5/11/15. Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

Full details of all the suggestions provided are given in appendix 3 for information.

**Table 3 Summary of suggested quality improvement areas**

| Suggested area for improvement | Stakeholders |
|---|---|
| **Serological testing**<br>• Serological testing for at risk groups<br>• Serological test standards | <br>DUK, SCM2, SCM3, CUK, SCM4<br>SCM2, SCM3 |
| **Patient information about diagnosis** | SCM3, CUK |
| **Referral of people with suspected coeliac disease**<br>• Referral to a specialist<br>• Access to endoscopy | <br>SCM3, CUK<br>BSG, SCM1, SCM2, BSNA |
| **Dietary management**<br>• Access to advice<br>• Vitamin D supplement | <br>BSG, SCM1, SCM2, BSNA, SCM3, CUK, SCM4<br>HQT |
| **Monitoring and follow-up**<br>• Annual review<br>• Non-responsive coeliac disease | <br>BSG, SCM1, BSNA, SCM3, CUK<br>CUK |
| **Additional areas**<br>• Prescriptions for gluten free foods<br>• Food labelling<br>• Cutaneous symptoms | <br>SCM2, SCM3, CUK, BCCG, BSNA<br>BAD<br>BAD |
| BAD, British Association of Dermatologists<br>BCCG, Barnsley CCG<br>BSG, British Society of Gastroenterology<br>BSNA, British Specialist Nutrition Association<br>CUK, Coeliac UK<br>DUK, Diabetes UK<br>HQT, HQT Diagnostics<br>SCM, Specialist Committee Member | |

## *3.2 Identification of current practice evidence*

Bibliographic databases were searched to identify examples of current practice in UK health and social care settings; 184 studies were identified for coeliac disease. In addition, current practice examples were suggested by stakeholders at topic engagement (6 studies) and internally at project scoping (1 study).

Of these studies, 12 were assessed as having potential relevance to this topic and the suggested areas for quality improvement identified by stakeholders (see appendix 2). A summary of relevant studies is included in the current practice sections for each suggested area of improvement.

# 4 Suggested improvement areas

## *4.1 Serological testing*

### 4.1.1 Summary of suggestions

**Serological testing for at risk groups**

Stakeholders suggested that people in at risk groups, such as those with Type 1 diabetes, irritable bowel disease and autoimmune thyroid disease, should have serological testing for coeliac disease. Coeliac disease is currently under diagnosed and there is a risk of serious complications including osteoporosis and intestinal lymphoma if diagnosis is delayed. Lack of recognition can also lead to repeated GP appointments and unnecessary investigations and interventions and poor quality of life.

It was also suggested that regular serological testing should be offered to those with Type 1 diabetes who initially test negative for coeliac disease as symptoms may not be apparent and prevalence is high.

**Serological test standards**

Stakeholders indicated that there is currently variation in standards for serological tests and in the communication of patient results.

### 4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 4 to help inform the Committee’s discussion.

**Table 4 Specific areas for quality improvement**

| Suggested quality improvement area | Suggested source guidance recommendations |
|---|---|
| Serological testing for at risk groups | **Recognition of coeliac disease**<br>NICE NG20 Recommendations 1.1.1 (KPI) and 1.1.6 |
| Serological test standards | **Serological testing for coeliac disease**<br>NICE NG20 Recommendations 1.2.2 (KPI), 1.2.3 (KPI), 1.2.4 and 1.2.7 |

## Recognition of coeliac disease

NICE NG20 Recommendation 1.1.1 (KPI)

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
    - type 1 diabetes, at diagnosis
    - autoimmune thyroid disease, at diagnosis
    - irritable bowel syndrome (in adults)
- first-degree relatives of people with coeliac disease.

NICE NG20 Recommendation 1.1.6

Advise people who have tested negative for coeliac disease, particularly first-degree relatives and people with type 1 diabetes, that:

- coeliac disease may present with a wide range of symptoms **and**
- they should consult their healthcare professional if any of the symptoms listed in recommendations 1.1.1 or 1.1.2 arise or persist.

## Serological testing for coeliac disease

NICE NG20 Recommendation 1.2.2 (KPI)

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 deamidated gliadin peptide (DGP) or IgG tTG if IgA is deficient.

NICE NG20 Recommendation 1.2.3 (KPI)

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

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

NICE NG20 Recommendation 1.2.4

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

NICE NG20 Recommendation 1.2.7

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

### 4.1.3 Current UK practice

**Serological testing for at risk groups**

A study using records from the General Practice Research database[2] found that people with coeliac disease were at least three times more likely than controls to have a prior diagnosis of irritable bowel syndrome (IBS). 28% of people with coeliac disease appeared to have been treated for IBS compared with 9% of controls. Although many of the diagnoses of IBS occurred within the last year before a diagnosis of coeliac disease, there was a clear excess of IBS 10 years earlier. The study concluded that in the UK it is likely that at least some patients with coeliac disease spend many years being treated as having IBS. This is an indication that some adults diagnosed with IBS are not being offered serological testing for coeliac disease in line with current guidance.

An audit of patients diagnosed with IBS at a large semi-rural general practice[3] found that only 26% of 250 patients were tested for coeliac disease. The study concluded that patients diagnosed with IBS in primary care are not routinely tested for coeliac disease.

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[2] Card et al (2013) An excess of prior irritable bowel syndrome diagnoses or treatments in Celiac disease: evidence of diagnostic delay Scandinavian Journal of Gastroenterology 48: 801-807

[3] Cooke et al (2014) An audit of testing for coeliac disease in patients diagnosed with the irritable bowel syndrome at a large primary care centre 0.1136/gutjnl-2014-307263.422

The National Paediatric Diabetes audit report 2013-14 reported that 43.7% of children with Type 1 diabetes in England had been screened for coeliac disease compared to 55% in Wales. Across England the region with the most comprehensive screening for coeliac disease was South Central (62.7%) while only 29.1% were screened in the North East.

A retrospective analysis of 159 children with Type 1 diabetes at Addenbrooke's Hospital in 2013[4] found that although the large majority had been screened for coeliac disease, only 47.2% were tested at diagnosis with the others tested at a later opportunity. The majority of those tested at diagnosis presented via the emergency department compared with just 8.8% of those presenting via other routes.

Several studies indicate that it is common practice to undertake endoscopy without prior serological testing:

- An audit carried out at a District General Hospital in 2011[5] concluded that patients with iron deficiency anaemia and suspected coeliac disease often undergo oesophago-gastroduodenoscopy and duodenal biopsy as a routine procedure without prior serum coeliac screening (only 16.7% had prior screening).

- A retrospective review of patients who had duodenal biopsies at Sandwell hospital[6] found that 59% of patients did not have serological testing for coeliac disease beforehand. The study also found that 38% of patients had a biopsy despite a negative serology test. The study concluded that £6695 would have been saved for this patient cohort if guidelines were followed.

- A small retrospective study of 40 biopsies in 3 teaching hospitals[7] found that serology was not carried out prior to biopsy in 81% of patients. The study concluded that current practice is unnecessarily exposing people to the risk of an endoscopy.

### Serological test standards

No published studies on current practice were found for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

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[4] Atherton et al (2014) Coeliac disease in children with Type 1 diabetes: Are current guidelines proving difficult to implement in practice? JPGN Vol 59 No 5

[5] Khatri et al (2012) Oesophago-gastroduodenoscopy yield in patients with coeliac disease presenting with iron deficiency anaemia: A re-audit doi:10.1136/gutjnl-2012-302514c.217

[6] Theron et al (2013) What is the cost of duodenal biopsies in patients without serological evidence of coeliac disease Gut June 2013Vol 62 (Suppl 1)

[7] Sorkin & Osborn (2014) Coeliac disease diagnosis: Compliance with NICE guidance Virchows Archiv.Conference: 26th European Congress of Pathology of the European Society of Pathology

## *4.2 Patient information about diagnosis*

### 4.2.1 Summary of suggestions

The importance of providing information to the patient about the diagnosis process and the need to maintain a gluten-containing diet was highlighted as a priority in order to ensure a diagnosis can be confirmed or eliminated.

### 4.2.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

**Table 5 Specific areas for quality improvement**

| Suggested quality improvement area | Suggested source guidance recommendations |
|---|---|
| Patient information | **Recognition of coeliac disease**<br>NICE NG20 Recommendations 1.1.3 (KPI) and 1.1.4 |

**Recognition of coeliac disease**

<u>NICE NG20 Recommendation 1.1.3 (KPI)</u>

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 **and**
- advise the person not to start a gluten-free diet until diagnosis is confirmed by a specialist, even if the results of a serological test are positive.

<u>NICE NG20 Recommendation 1.1.4</u>

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.

### 4.2.3 Current UK practice

No published studies on current practice were found for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

## *4.3 Referral of people with suspected coeliac disease*

### 4.3.1 Summary of suggestions

**Referral to a specialist**

Stakeholders suggested that it is important for people with a positive serological test to be referred to a specialist for further investigations to confirm the diagnosis. It was highlighted that children should be referred to a specialist paediatrician with an interest in gastroenterology.

**Access to endoscopy**

There was concern about long waiting times between a positive serology test and endoscopy because referrals may be identified as routine which can mean a wait of 2 months. During that time patients may revert to a gluten-free diet before the diagnosis is confirmed. A delayed diagnosis can result in continuing ill health and long-term complications. It was suggested that endoscopy should be undertaken within 2 weeks.

### 4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 6 to help inform the Committee's discussion.

**Table 6 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Referral to a specialist | **Referral of people with suspected coeliac disease**<br>NICE NG20 Recommendations 1.3.1 and 1.3.2 |
| Access to endoscopy | Not directly covered in NICE NG20 and no recommendations are presented |

**Referral of people with suspected coeliac disease**

<u>NICE NG20 Recommendation 1.3.1</u>

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

NICE NG20 Recommendation 1.3.2

Refer children with positive serological test results to a paediatric gastroenterologist or paediatrician with a specialist interest in gastroenterology for further investigation for coeliac disease.

### 4.3.3 Current UK practice

**Referral to a specialist**

A review of 6394 coeliac serology tests performed at a large district general hospital laboratory in Bournemouth over 12 months in 2010-11[8] indicated that 21.6% of 100 positive results did not have gastroenterological follow-up arranged. 16 of the 22 patients who did not have gastroenterological follow-up arranged had their serology tests arranged in primary care.

**Access to endoscopy**

A review of quality outcome measures for children with coeliac disease at two hospitals in the East of England[9] found that one of two hospitals did not achieve a target for 90% to have a 'biopsy within four weeks of positive serology result' due to waiting times for endoscopy that prevented more prompt scheduling of biopsy. The study notes however that there have been changes to the diagnostic guidelines allowing the diagnoses of coeliac disease in children to be made without the requirement of a small bowel biopsy.

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[8] Kodjabashia et al (2012) Coeliac serology at a large district general hospital, results in 6394 patients doi:10.1136/gutjnl-2012-302514d.113

[9] Ross et al (2013) Assessing Quality Outcome Measures in Children with Coeliac Disease—Experience from Two UK Centres Nutrients 2013, 5, 4605-4613

## *4.4 Dietary management*

### 4.4.1 Summary of suggestions

**Access to advice**

Stakeholders suggested that people with coeliac disease should have prompt (e.g. within 2 or 6 weeks) access to advice about a gluten free diet from a dietitian following diagnosis.

**Vitamin D supplement**

There was a suggestion that Vitamin D levels should be tested in primary care and supplemented to between 100-150 nmol/L because high levels of Vitamin D can reduce inflammation of the gut.

### 4.4.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

**Table 7 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Dietary advice | **Information and support**<br>NICE NG20 Recommendations 1.6.2 and 1.6.3 (KPI)<br>**Dietitian contribution to patient management**<br>NICE NG20 Research Recommendation 4 |
| Vitamin D | **Advice on dietary management**<br>NICE NG20 Recommendation 1.7.2<br>**Dietary supplements**<br>NICE NG20 Research Recommendation 3 |

**Information and support**

<u>NICE NG20 Recommendation 1.6.2</u>

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

NICE NG20 Recommendation 1.6.3 (KPI)

A healthcare professional with a specialist knowledge of coeliac disease should tell people with a confirmed diagnosis of coeliac 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 and suitable alternatives, including gluten-free substitutes
- 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 national and local coeliac support groups.

### Dietitian contribution to patient management

NICE NG20 research recommendation 4

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's role in helping people with coeliac disease to adhere to a gluten‑free diet.

### Advice on dietary management

NICE NG20 Recommendation 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.

### Dietary supplements

NICE NG20 research recommendation 3

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.

## 4.4.3 Current UK practice

### Access to advice

Stakeholders suggested that there is currently a shortage of dietitians. Some suggested there is a need for an increase in the number of dietitians. Others gave examples of local areas that are trying new models of providing dietary advice including group clinics with one to one follow-up either face to face or by phone or online.

Service re-design of a dietetic led coeliac service to include group education and one to one appointments in Gloucestershire[10] has been successful in reducing waiting times with the majority of patients seen within 8 weeks and many within 4 weeks of referral. The group environment also provides patients the opportunity of meeting others in a similar situation, reducing isolation and allows shared experience of practical tips and local information, which may help to improve adherence to the gluten free diet.

An audit of a nurse led clinic for patients with coeliac disease in Aintree[11] found that only 14% were referred to a dietitian at the point of diagnosis. Following the

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[10] Gloucestershire Hospitals NHS Foundation Trust A dietetic-led coeliac service incorporating group education NICE shared learning database

[11] Bapen (2012) Dietetic led coeliac clinic

development of a dietetic led care pathway coeliac patients are seen by a dietitian within 12 weeks of diagnosis usually at a group meeting.

### Vitamin D supplement

No published studies on current practice were found for this suggested area for quality improvement; this area is based on stakeholder’s knowledge and experience.

## *4.5 Monitoring and follow-up*

### 4.5.1 Summary of suggestions

**Annual review**

Stakeholders indicated that people with coeliac disease should have an annual review in order to monitor adherence to treatment, review symptoms and assess any additional support needs. People at risk of long term complications should be referred for further support.

**Non-responsive coeliac disease**

It was highlighted that people with non-responsive coeliac disease should be reviewed and referred to a specialist for further investigation if required.

### 4.5.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 8 to help inform the Committee's discussion.

**Table 8 Specific areas for quality improvement**

| Suggested quality improvement area | Selected source guidance recommendations |
|---|---|
| Annual review | **Monitoring in people with coeliac disease**<br>NICE NG20 Recommendations 1.4.3 (KPI) and 1.4.4 |
| Non-responsive coeliac disease | **Non-responsive and refractory coeliac disease**<br>NICE NG20 Recommendations 1.5.1 (KPI) and 1.5.3 |

**Monitoring in people with coeliac disease**

NICE NG20 Recommendation 1.4.3 (KPI)

Offer an annual review to people with coeliac disease. During the review:

- measure weight and height
- review symptoms
- consider the need for assessment of diet and adherence to the gluten-free diet

- consider the need for specialist dietetic and nutritional advice.

NICE NG20 Recommendation 1.4.4

Refer the person to a GP or consultant if concerns are raised in the annual review. The GP or consultant should assess all of the following:

- the need for a dual-energy X-ray absorptiometry (DEXA) scan (in line with the NICE guideline on osteoporosis: assessing the risk of fragility fracture) or active treatment of bone disease
- the need for specific blood tests
- the risk of long-term complications and comorbidities
- the need for specialist referral.

**Non-responsive and refractory coeliac disease**

NICE NG20 Recommendation 1.5.1 (KPI)

Consider the following actions 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 the person 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.

NICE NG20 Recommendation 1.5.3

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

### 4.5.3 Current UK practice

**Annual review**

Stakeholders suggested that new models of pharmacy or dietitian – led monitoring of people with coeliac disease have the potential to provide cost effective service improvement to support access to annual reviews.

A review of a dietitian led virtual coeliac disease clinic (questionnaire, blood test and telephone follow up/referral if required) at The Royal Bournemouth Hospital[12] concluded that it was a cost effective and patient preferred method of managing adults with coeliac disease. 80% of patients indicated that alternating annually between virtual review and a clinic appointment was preferential to an annual clinic appointment.

## Non-responsive coeliac disease

No published studies on current practice were found for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

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[12] Stuckey et al (2014) Dietitian-led virtual coeliac disease clinic results in cost savings and increased patient satisfaction Gut 2014:63 (Suppl 1)

## *4.6 Additional areas*

### Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise. However they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 16th December 2015.

### Prescriptions for gluten free foods

Stakeholders indicated that access to gluten free substitute food on prescription is important to support adherence, especially in children. This was felt to be important because gluten-free substitute foods such as bread can be expensive and are only available from larger retailers. Another stakeholder suggested that the supply of gluten free foods on prescription should be stopped or reduced as a wider range of products are now available in large supermarkets. It was suggested this would reduce NHS costs. Prescribing for gluten free foods is included within guidance from the Advisory Committee for Borderline Substances and is not included in the development source (NICE NG20).

### Food labelling

It was suggested that the optimisation of food labelling is a key area for quality improvement. Food labelling is outside the remit of NICE and is not covered within the development source (NICE NG20).

### Cutaneous symptoms

A stakeholder suggested that addressing cutaneous symptoms is a key area for quality improvement. The treatment of dermatitis herpetiformis is not covered within the development source (NICE NG20).

## Appendix 1: Key priorities for implementation (NG20)

Recommendations that are key priorities for implementation in the source guideline and that have been referred to in the main body of this report are highlighted in grey.

### *Recognition of coeliac disease*

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
    - type 1 diabetes, at diagnosis
    - autoimmune thyroid disease, at diagnosis
    - irritable bowel syndrome (in adults)
- first-degree relatives of people with coeliac disease.

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 **and**
- advise the person not to start a gluten-free diet until diagnosis is confirmed by a specialist, even if the results of a serological test are positive.

### *Serological testing for coeliac disease*

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 deamidated gliadin peptide (DGP) or IgG tTG if IgA is deficient.

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

- test for total IgA and IgA tTG, as the first choice

- consider using IgG EMA, IgG DGP or IgG tTG if IgA is deficient.

### Monitoring in people with coeliac disease

Offer an annual review to people with coeliac disease. During the review:

- measure weight and height
- review symptoms
- consider the need for assessment of diet and adherence to the gluten‑free diet
- consider the need for specialist dietetic and nutritional advice.

### Non‑responsive and refractory coeliac disease

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

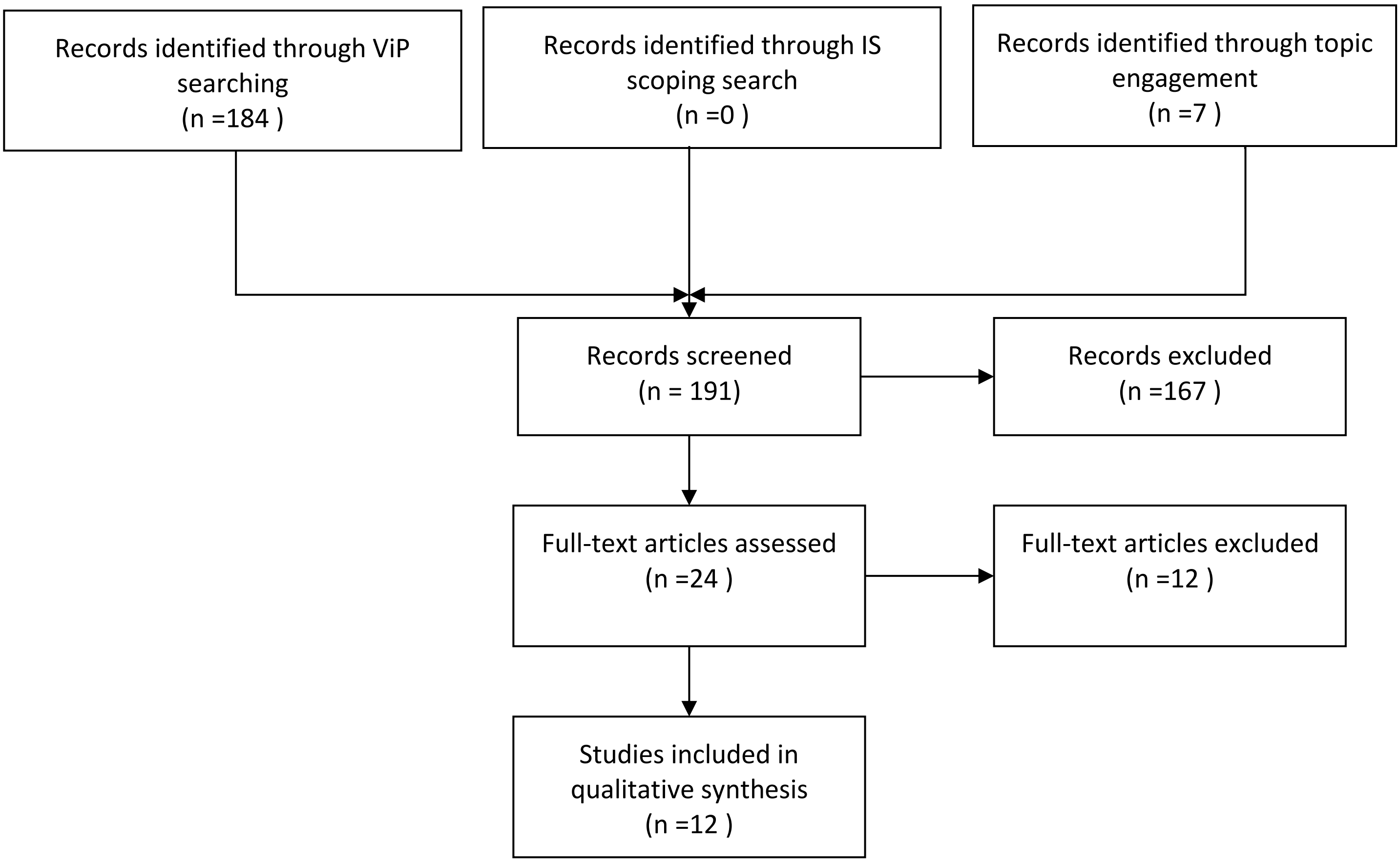
- review the certainty of the original diagnosis
- refer the person to a specialist dietitian to investigate continued exposure to gluten
- investigate potential complications or coexisting conditions that may be causing persistent symptoms, such as irritable bowel syndrome, lactose intolerance, bacterial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

### Information and support

A healthcare professional with a specialist knowledge of coeliac disease should tell people with a confirmed diagnosis of coeliac 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 and suitable alternatives, including gluten‑free substitutes
- 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 national and local coeliac support groups.

# Appendix 2: Review flowchart



## Appendix 3: Suggestions from stakeholder engagement exercise – registered stakeholders

| ID | Report Section | Stakeholder | Suggested key area for quality improvement | Why is this important? | Why is this a key area for quality improvement? | Supporting information |
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| 1 | 4.1 | Diabetes UK | Implementation of clear guidelines for conducting regular serological testing for coeliac disease in people with Type 1 diabetes | Clear guidelines should be implemented in order to ensure that people with Type 1 diabetes are required to undergo serological screening for coeliac disease at regular and appropriate intervals. Such guidelines should, moreover, specify a timeframe for repeat serological testing at regular intervals in addition to at the point of diagnosis of Type 1 diabetes. | There is a high prevalence of coeliac disease amongst people with Type 1 diabetes. Indeed, coeliac disease is more common in people who already have Type 1 diabetes, as both are autoimmune conditions and so are genetically linked.<br>Some people with Type 1 diabetes find it is only after starting insulin that the symptoms of coeliac disease become noticeable. Some people with Type 1 diabetes have a 'silent' form of coeliac disease, which means no symptoms are apparent and it is only diagnosed by screening.<br>The low diagnostic rate and the fact that many people are asymptomatic, combined with the higher rates of coeliac disease amongst people with Type 1 diabetes makes regular serological testing extremely important for them. | Please see https://www.diabetes.org.uk/Guide-to-diabetes/What-is-diabetes/Related-conditions/ |
| 2 | 4.1 | SCM2 | Key area for quality | Guidance from NICE for | Coeliac disease is common and | See papers from our |

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| | | | improvement 1<br>Speed of recognition of the condition – at health care level – primary and secondary care | implementation relating to the recommended screening tests and reporting of test results, at risk groups and pathway for screening for coeliac disease. Failure to recognise coeliac disease can result in more serious complications of the disease including osteoporosis and intestinal lymphoma, as well as resulting in continuing ill health and uncertainty. Failure to recognise coeliac disease can also result in repeated GP appointments and associated investigations and wrong interventions over a significant period of time impacting on NHS budgets as well as quality of life of the patient. | has a prevalence of 1 in 100 but currently there is under diagnosis. The symptoms of coeliac disease are missed and treated as IBS and diagnosis is often delayed, in adults up to 13 years and tens (30 on average) of visits to health care services– if calculated this must be huge cost to the NHS and wasted time for GPs. Delayed diagnosis increases the risk of complications and health problems which may not be reversed. Untreated coeliac disease is associated with a higher risk of complications. Standards for blood tests and notification of patient results both vary. | group as evidence.<br>See paper from West et all attached to e-mail with submission. |
| 3 | 4.1 | SCM3 | Key area for quality improvement 1<br>Screening those at risk of coeliac disease: implementation of NICE guidance. | There is clear guidance from NICE for implementation relating to the recommended screening tests and reporting of test results, at risk groups and pathway for screening for coeliac disease. Failure to recognise coeliac disease can result in more serious complications of the disease including osteoporosis and intestinal lymphoma, as well as resulting in continuing ill health and uncertainty [1]. Failure to | Coeliac disease is common and has a prevalence of 1 in 100 but currently there is under diagnosis with three quarters of the population in the UK unrecognised [3]. The symptoms of coeliac disease are missed and treated as IBS [4] and diagnosis is delayed, occurring more commonly in the fifth and sixth decades of a person's life [3]. Delayed diagnosis increases the risk of complications and health problems which may not be | 1. NICE, *Clinical guidance NG20, Coeliac disease; recognition, assessment and management.* 2015.<br>2. Violato, M., et al., *Resource use and costs associated with coeliac disease before and after diagnosis in 3,646 cases: results of a UK primary care database analysis.* |

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| | | | | recognise coeliac disease can also result in repeated GP appointments and associated investigations over a significant period of time impacting on NHS budgets as well as quality of life of the patient [2] | reversed. Untreated coeliac disease is associated with a higher risk of complications [1]. Standards for blood tests and notification of patient results both vary. | PLoS One, 2012. **7**(7): p. e41308.<br>3. West, J., et al., *Incidence and prevalence of celiac disease and dermatitis herpetiformis in the UK over two decades: population-based study.* Am J Gastroenterol, 2014. **109**(5): p. 757-68.<br>4. Card, T.R., et al., *An excess of prior irritable bowel syndrome diagnoses or treatments in Celiac disease: evidence of diagnostic delay.* Scand J Gastroenterol, 2013. **48**(7): p. 801-7. |
| 4 | 4.1 | Coeliac UK | Key area for quality improvement 1<br>In order to improve diagnosis rates, healthcare professionals should have a low threshold for screening for coeliac disease | Coeliac disease is a common condition which affects 1 in 100 people in the UK [1]. There is a well-established diagnosis pathway and associated investigations (antibody blood tests and endoscopy) for coeliac disease which is set out in national clinical guidelines [2]. Undiagnosed coeliac disease can result in continued ill health and an increased risk of serious | Although coeliac disease affects 1 in 100 people, only 24% of people with the condition are currently diagnosed [3]. Research shows that 1 in 4 people with coeliac disease have previously received treatment for irritable bowel syndrome (IBS) [4] and therefore it is likely that coeliac disease is often misdiagnosed as IBS. Securing a diagnosis of coeliac disease can take many years and | 1] Bingley PJ, 1.Williams AJ, Norcross AJ et al. (2004) Undiagnosed coeliac disease at age seven: population based prospective birth cohort study. BMJ 328(7435): 322–3. doi:http://dx.doi.org/10.1136/bmj.328.7435.322 |

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| | | | | long term complications including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency [2]. | on average it takes 13 years for patients to secure a diagnosis [5]. In order to help patients to secure a diagnosis earlier, healthcare professionals should have a low threshold for testing and should offer serological testing to people with the symptoms or associated conditions as listed in recommendation 1.1 of the NICE guideline [2]. | [2] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management 2015<br>[3] West J, Fleming KM, Tata LJ et al. (2014) Incidence and Prevalence of Celiac Disease and Dermatitis Herpetiformis in the UK Over Two Decades: Population-Based Study. Am J Gastroenterol 109:757-768<br>[4] Card TR, Siffledeen J, West J et al. (2013) An excess of prior irritable bowel syndrome diagnoses or treatments in Celiac disease: evidence of diagnostic delay. Scand J Gastroenterol **48**(7): 801–7. doi: 10.3109/00365521.20 |

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| | | | | | | 13.786130<br>[5] Gray AM & Papanicolas IN (2010) Impact of symptoms on quality of life before and after diagnosis of coeliac disease: results from a UK population survey. BMC Health Serv Res **10**: 105. doi:10.1186/1472-6963-10-105 |
| 5 | 4.1 | SCM4 | Key area for quality improvement 2<br>CD Case-finding | Coeliac Disease (CD) Case-finding in General Practice in Irritable Bowel Syndrome(IBS), Type 1 Diabetes and Autoimmune thyroid disease. | CD is under-diagnosed.<br>The GDG evidence review found that case-finding should happen for these three conditions. IBS is a very common diagnosis both in Primary care. All 3 conditions can be easily audited in General Practice to ascertain previous CD serology testing. Patients not previously tested should be offered testing. | |
| 6 | 4.2 | SCM3 | Key area for quality improvement 3<br>Accurate patient information on the diagnosis process | NICE outlines the necessary information on the diagnosis process and the associated requirement relating to the maintenance of a gluten-containing diet throughout the process and steps to take when gluten has been excluded from the diet [1]. | Without accurate information throughout the diagnosis process regarding testing, referral and the importance of maintaining a gluten-containing diet there is the potential for confusion and failure to complete the necessary steps and conclusively confirm or eliminate diagnosis of coeliac | 1. NICE, *Clinical guidance NG20, Coeliac disease; recognition, assessment and management.* 2015. |

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| | | | | | disease. | |
| 7 | 4.2 | British Society of Gastroenterology | Key area for quality improvement 1 | Patients with a positive blood test for coeliac disease may be graded as routine for endoscopy. This may mean they wait for more than 2 months for their test. A positive EMA antibody has a >90% chance of having coeliac disease. | Recommend that any individual with a positive EMA blood test or TTG > 10x normal should have a gastroscopy and duodenal biopsy within 2 weeks | No additional information provided |
| 8 | 4.2 | SCM1 | Key area for quality improvement 1 | Patients with a positive blood test for coeliac disease may be graded as routine for endoscopy. This may mean they wait for more than 2 months for their test. A positive EMA antibody has a >90% chance of having coeliac disease. | Recommend that any individual with a positive EMA blood test or TTG > 10x normal should have a gastroscopy and duodenal biopsy within 2 weeks | Sinclair H J Clin Path 2003 |
| 9 | 4.2 | SCM2 | Key area for quality improvement 2<br>Speed of relay of positive results to gastroenterology service and prioritisation of endoscopic assessment to confirm diagnosis | Streamlining the testing and reporting system should happen – think of the delays in the process ie gp sends sample to lab, lab reports back to gp then referral to to gi service…..this is cumbersome and wastes time – if a patient's result was relayed to a designated member of a regional or local team, then the process can be improved – this would be easily auditable | Wasted time around the process will result (does result) in people not being notified, delays in notification, patients then deciding to do gluten free without biopsy. This is a disaster.<br>We have the lab report to the local lead for the condition – this could be a nurse specialist or better still a specialist dietitian- who co-ordinates the notification and arranges the endoscopy and follow up – this would make the patient journey quicker and much more time efficient for health care | See papers from our group.<br>http://www.ncbi.nlm.nih.gov/pubmed/22060243<br>http://www.biomedcentral.com/1471-230X/11/118 |

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| | | | | | services | |
| 10 | 4.2 | British Specialist Nutrition Association | Prompt/rapid endoscopic investigation for coeliac disease | At present, the time between a serological screening test for coeliac disease and the endoscopic investigation is variable across the country as there are no guidelines in place. This often results in delays in initiation of treatment and in some patients may mean treatment is self-initiated prior to confirmation of diagnosis (via endoscopic variation). | A delayed diagnosis, or undiagnosed coeliac disease, can result in continuing ill health and serious long-term complications. In addition, there is no baseline from which to assess ongoing symptoms in cases where diagnosis has not been confirmed yet symptoms persist. These issues should largely be resolved by establishing a prompt and standard timeframe between screening test and endoscopic investigation. | No additional information provided |
| 11 | 4.2 | SCM3 | Key area for quality improvement 2<br>Referral from primary to secondary care for completion of diagnosis process in coeliac disease | NICE has developed a care pathway for diagnosis of coeliac disease which outlines the necessary investigations and referral to specialist gastroenterology. For children it is important that they are referred to a specialist paediatrician with an interest in gastroenterology. The diagnosis of coeliac disease involves serological testing which may be done in primary care and in adults and some children endoscopy with biopsy which generally occurs in secondary care [1]. | Failure to refer for appropriate investigations and to specialist units in line with NICE may impact on confirmation of diagnoses. Long waiting times between screening and referral for endoscopy may result in patients with positive antibody tests reverting to the gluten-free diet themselves. | 1. NICE, *Clinical guidance NG20, Coeliac disease; recognition, assessment and management.* 2015. |
| 12 | 4.2 | Coeliac UK | Key area for quality | Endoscopy with duodenal | Local pathways should allow for | |

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| | | | improvement 2<br>People with positive serology for coeliac disease should receive a prompt referral for endoscopy. | biopsy is essential to confirm diagnosis of adults with coeliac disease. It is important that people with positive serology for coeliac disease are referred for endoscopy promptly in order to confirm the diagnosis and initiate treatment as soon as possible. Children with suspected coeliac disease should be referred to a paediatric gastroenterologist for further investigation, including HLA testing, if necessary. | referral for endoscopy to be performed quickly and efficiently to ensure that a diagnosis of coeliac disease can be made without delay so that the gluten-free diet can be initiated in a timely manner. In the short term, a delay in diagnosis and therefore initiation of the gluten-free diet results in continuing symptoms for the patients and in the long term is associated with an increased risk of complications.<br>A delay in referral for endoscopy may result in some patients commencing the gluten-free diet in an attempt to alleviate symptoms. As biopsy results are dependent on the patient eating a gluten containing diet, it is essential that patients are educated on the importance of continuing a normal, gluten containing diet until a diagnosis is confirmed. | |
| 13 | 4.3 | British Society of Gastroenterology | Key area for quality improvement 2 | A GFD is the cornerstone for improving patients symptoms and avoiding complications | All patients with Coeliac Disease should see a dietitian within 2 weeks of the diagnosis | No additional information provided |
| 14 | 4.3 | SCM1 | Key area for quality improvement 2 | A GFD is the cornerstone for improving patients symptoms and avoiding complications | All patients with Coeliac Disease should see a dietitian within 6 weeks of the diagnosis | No additional information provided |
| 15 | 4.3 | SCM2 | Key area for quality improvement 3 | Gluten-free diet is the only treatment for cd. it provides an | Specialist dietitians, as per recent NICE guidance on diagnosis and | http://gut.bmj.com/content/63/Suppl_1/A219. |

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| | | | Time to see a dietitian – actually seeing a dietitian , the value of dietetic management longterm! | effective intervention which is low cost to the nhs (in real terms). accurate, up-to-date knowledge by specialist dietitians as recommended by nice. in addition, access to gluten-free substitute foods via the nhs (on prescription) to aid adherence to the gluten-free diet. | management, are key to pre-peri and post- diagnosis management of a dietetically dependent condition.<br>The setting up of group clinics in our are has been highly successful but one to one meetings need to be offered for follow up. There is evidence that patients value this – this could be face to face or phone or virtual. | 2<br>http://www.bapen.org.uk/tackling-malnutrition/good-practice-in-nutritional-care/examples-of-good-practice-in-nutritional-care/hospital-services/dietetic-led-coeliac-clinic<br>http://www.magonlinelibrary.com/doi/abs/10.12968/gasn.2015.13.2.38 |
| 16 | 4.3 | SCM2 | Key area for quality improvement 4<br>Dietetic staffing to increase to cope with demand and to have offer of proper review and deliver education to patients, families and general practitioners | See above # 3 | | https://www.nice.org.uk/sharedlearning/a-dietetic-led-coeliac-service-incorporating-group-education<br>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3756800/ |
| 17 | 4.3 | British Specialist Nutrition Association | Proven diagnosis of coeliac disease | A quick and fixed pathway to diagnosis is highly important. A diagnosis of coeliac disease | A quick and fixed pathway to diagnosis ensures a secure diagnosis from which treatment (a | NICE Clinical Guideline 20 recommends that a |

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| | | | | must be confirmed via endoscopic investigation by a gastroenterologist following a serological screening test (patient must be on a gluten-containing diet). | strict lifelong gluten-free diet) can be initiated. This also provides a baseline from which it is possible to assess ongoing symptoms in cases where symptoms persist. | healthcare professional with a specialist knowledge of coeliac disease should inform people with a confirmed diagnosis about the importance of a gluten-free diet and provide them with information to help them follow it, ideally at or as soon after confirmation of diagnosis as possible. |
| 18 | 4.3 | SCM3 | Key area for quality improvement 4<br>Dietary management post diagnosis | The medical treatment for coeliac disease, the gluten-free diet provides an effective intervention which is low cost to the NHS but it requires the transfer of accurate, up-to-date knowledge by specialist dietitians as recommended by NICE. In addition, access to gluten-free substitute foods via the NHS (on prescription) to aid adherence to the gluten-free diet [1] | Patients are not getting timely or adequate referral to specialist dietitians, either at diagnosis or for ongoing support and review. There is a lack of dietetic resource within the NHS that needs to be addressed [5]. Dietitians should be encouraged to meet necessary standards of experience/expertise relating to coeliac disease management and gluten-free diet therapy.<br>Gluten-free substitute foods eg bread are significantly more expensive than standard products in retail and availability is limited to larger supermarkets and chains [6] [7]. This is a particular concern in England where local policy | 1. NICE, *Clinical guidance NG20, Coeliac disease; recognition, assessment and mangement.* 2015.<br>5. Nelson, M., N. Mendoza, and N. McGough, *A survey of provision of dietetic services for coeliac disease in the UK.* J Hum Nutr Diet, 2007. **20**(5): p. 403-11.<br>6. Singh, J. and K. Whelan, *Limited availability and higher cost of gluten-free foods.* J Hum Nutr |

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| | | | | | making is resulting in health inequalities with restricted or complete removal of access to gluten-free food on prescription in some parts of the country. | Diet, 2011. **24**(5): p. 479-86.<br>7. Burden, M., et al., *Cost and availability of gluten-free food in the UK: in store and online.* Postgrad Med J, 2015. **91**(1081): p. 622-6. |
| 19 | 4.3 | Coeliac UK | Key area for quality improvement 3<br>Support for maintaining the gluten-free diet through the provision of gluten-free food on prescription and access to dietetic services | The only medical treatment for coeliac disease is strict, lifelong adherence to the gluten-free diet.<br>Gluten-free substitute staple foods are provided on prescription to promote adherence to the highly restrictive gluten-free diet. A specialist dietitian is best placed to provide education about the gluten-free diet, including:<br>• How to access gluten-free food on prescription<br>• Food labelling<br>• Recipes<br>• Eating out<br>• Cross contamination | The gluten-free diet offers a complete treatment for coeliac disease, however adherence to the diet varies, with 20-80% of people with coeliac disease admitting to lapses [2]. Research has found that adherence to the gluten-free diet is improved with access to dietetic services and prescriptions for gluten-free staples [8].<br>Gluten-free food on prescription plays a vital role in adherence to the gluten-free diet as it improves access to gluten-free substitute foods. Gluten-free staple foods are 3-4 times the price of gluten containing equivalent and are not readily available in budget supermarkets and corner shops [6, 7]. Access to gluten-free food on prescription is therefore particularly important for people | [2] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management 2015<br>[6] Singh, J. & Whelan, K. (2011). Limited availability and higher cost of gluten-free foods. Journal of Human Nutrition and Dietetics, 24, 479-486.<br>[7] Burden, M., et al., Cost and availability of gluten-free food in the UK: in store and online. Postgrad Med J, 2015. 91(1081): p. |

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| | | | | | with limited transport option and those on fixed incomes.<br>The Guidelines Development Group for the NICE guidelines for recognition, assessment and management of coeliac disease [2] highlighted a resource gap for dietetic support. Local dietetic services should be assessed to ensure that newly diagnosed patients can be offered an appointment with a dietitian in a timely manner. | 622-6.<br>[8] Hall N, Rubin G & Charnock A (2013) Intentional and inadvertent non-adherence in adult coeliac disease. A cross-sectional survey. Appetite 68 56-62 |
| 20 | 4.3 | Coeliac UK | Additional developmental areas of emergent practice:<br>Innovation in providing dietetic support | The Guidelines Development Group for the NICE guidelines for recognition, assessment and management of coeliac disease [2] highlighted that there is a resource gap for dietetic support. Specialist dietitians are best placed to provide expert advice on the gluten-free diet and to improve patient access to dietitians, innovative new models should be explored to improve resource in dietetic departments. | In some parts of the country rapid post-diagnosis access to dietetic services is made feasible through group coeliac disease clinics. Such a model may be appropriate for wider use in the UK.<br>Other innovative approaches such as telephone appointments and app support should be considered as new methods to improve access to dietetic services. | [2] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management 2015 |
| 21 | 4.3 | SCM4 | Key area for quality improvement 1<br>Dietitian availability | The Guideline is clear that dietary adherence is a key component of annual review in people with CD.<br>General Practitioners have | Gluten free dietary adherence is crucial in CD to maintain health and wellbeing. Assessing dietary adherence is a specialism and dietitians are the only Healthcare | |

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| | | | | historically had no training in assessing the gluten free diet. There should be availability of specialist dietitians to assist with yearly reviews. | professionals trained in this area. Availability of dietitians is variable. | |
| 22 | 4.3 | SCM2 | Key area for quality improvement 5<br>Key issues around gluten free product availability | This is the only treatment – if it were a required medication there would be no argument – we have a postcode lottery in the UK in an attempt to save money. The schemes developed in Scotland are examples of properly funded but streamlined services that take the need for GPs out of the cumbersome current methodology | Availability in my personal experience is key to good adherence, especially in children. | See info in my e-mail from Scottish government re the GFFS |
| 23 | 4.3 | SCM2 | Additional developmental areas of emergent practice | Pharmacy led schemes such as Tayside scheme and Scottish GFFS are successful, streamlined and viable for cost effective care of patients with this condition | The use of App based service, online services are all innovative and creative services that should be looked at | https://www.taysideglutenfree.org.uk/ |
| 24 | 4.4 | British Society of Gastroenterology | Key area for quality improvement 3 | Clinical Follow up is required with a dietitian | Annual dietetic review | No additional information provided |
| 25 | 4.4 | SCM1 | Key area for quality improvement 3 | Clinical Follow up is required with a dietitian | Annual dietetic review | No additional information provided |
| 26 | 4.4 | British Specialist Nutrition Association | Standardised monitoring of patients with coeliac disease | It is widely recognised that follow-up of coeliac patients is very variable (and in some areas non-existent). | The establishment of an appropriate care pathway which encompasses an annual review by healthcare professionals (as recommended in NICE Guideline 20) would allow for monitoring of | NICE Clinical Guideline 20 recommends all people diagnosed with coeliac disease should have an |

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| | | | | | adherence to treatment and assessment of diet, need for specialist dietetic and nutritional advice and review of symptoms. | annual review. During the review all patients should have their weight and height measured, symptoms reviewed and consideration taken for the need for assessment of diet and adherence to the gluten-free diet, alongside the need for specialist dietetic and nutritional advice. |
| 27 | 4.4 | SCM3 | Key area for quality improvement 5<br>Monitoring people with coeliac disease | NICE guidance on management of coeliac disease is available and recommends offering patients with coeliac disease an annual review to monitor symptoms, weight, dietary adherence and the need for referral for specialist care. Ongoing review is vital to recognise cases of non-responsive coeliac disease [1] | In the absence of NICE guidance, annual review is not routinely being offered to patients with coeliac disease. Ongoing review of patients with coeliac disease is necessary to screen for nutritional deficiencies, other complications of coeliac disease and also development of associated conditions. | 1. NICE, *Clinical guidance NG20, Coeliac disease; recognition, assessment and mangement.* 2015 |
| 28 | 4.4 | SCM3 | Additional developmental areas of emergent practice | Pharmacy/dieteitian-led monitoring of patients with coeliac disease | Models are appearing and may provide potential for economical use of NHS resources and service development. | |
| 29 | 4.4 | Coeliac UK | Key area for quality improvement 4<br>Monitoring for persistent | Untreated coeliac disease is associated with ongoing symptoms and in the long term an increased risk of | Monitoring should include review of symptoms, weight and height, considering the need for assessment of diet and | [2] National Institute for Health and Clinical Excellence (2015) Coeliac disease: |

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| | | | symptoms, adherence to the diet and refractory coeliac disease | complications. It is recommended that people with coeliac disease should be offered an annual review [2]. This is to provide support in adhering to the diet and to identify those where the gluten-free diet is not having optimal outcome and where there could be a greater risk of complications | adherence to the gluten-free diet, the need for specific blood tests, the risk of long term complications and co-morbidities, the need for DEXA and the need for specialist referral, as listed in recommendation 1.4 of the NICE guideline.<br>People with coeliac disease may have persistent symptoms due to ongoing gluten ingestion, misdiagnosis of coeliac disease or complications or coexisting conditions such as Irritable Bowel Syndrome, lactose intolerance, bacterial overgrowth, microscopic colitis or inflammatory colitis or refractory coeliac disease. In cases where people present with non-responsive coeliac disease this should be reviewed as per recommendation 1.5 of the NICE guideline [2]. | recognition, assessment and management 2015 |
| 30 | 4.4 | Coeliac UK | Key area for quality improvement 5<br>Appropriate regular monitoring with clear pathways for referral for patients at risk of long term complications | It is recommended that people with coeliac disease should be offered an annual review [2]. Follow up involves a multidisciplinary team and will be dependent on concerns raised in the initial appointment and annual review.<br>The development of a pathway for referral and triage would support effective follow up and | In follow up, people with coeliac disease should receive appropriate referral to dietitians, GP, consultant or psychologist when concerns are raised.<br>• During the review the need for assessment of diet and adherence to the gluten-free diet, and the need for specialist dietetic and nutritional advice should be considered, as listed in | [2] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management 2015 |

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| | | | | referral to the relevant healthcare professionals. As there is variation across the UK on follow up, local involvement could support meeting the quality standard under local resources. | recommendation 1.4.3 of the NICE guideline. With 20-80% of people admitting to lapses on the gluten-free diet, a dietitian is well placed to review patients for adherence to the diet.[2]<br>• Recommendation 1.4.1 and 1.4.2 of the NICE guideline supports referral to a GP or consultant if concerns are raised in the annual review and recommends assessment of the need for dual-energy X-ray absorptiometry (DEXA), the need for specific blood tests, the risk of long term complications and the need for specialist referral.[2]<br>• In cases of refractory coeliac disease, recommendation 1.5.3 supports referral to a specialist centre for further investigation.[2]<br>• Clinicians should be aware that people with coeliac disease may experience anxiety and depression as listed in recommendation 1.6.4 of the NICE guideline.[2] | |
| 31 | 4.4 | HQT Diagnostics | General Practitioners should test and supplement Vitamin D 25(OH)D to between 100- | There is good evidence that increased levels of Vitamin D help Coeliac patients | High levels of Vitamin D reduce many gut problems, including Inflammation | See more:<br>http://www.vitamindwiki.com/Overview+Gut+and+vitamin+D |

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| | | | 150 nmol/L for all Coeliac patients and review blood tests after 3 months | | | http://greenvits.eu/collections/vitamin-d |
| 32 | 4.5 | Barnsley CCG | Key area for quality improvement 1:<br>Cost reduction to the NHS prescribing budget by stopping / reducing the supply of Gluten free health products on prescription | This aspect of the Guidance will help support a more cost effective way of managing the disease post diagnosis.<br>Health food (gluten free) products are now widely available in the majority of large supermarkets.<br>A larger variety of gluten free foods are now available giving the patients greater choice and variation of diet (which is not always accommodated when prescribed on the NHS) | This will ultimately free up funds from individual CCGs prescribing budget which can then be utilised in other areas of the health economy. | North Norfolk CCG have now implemented a program to remove all Gluten free products from their formulary as these products are now widely available via any supermarket chain.<br>http://www.northnorfolkccg.nhs.uk/news/ccg-statement-gluten-free-foods<br>The cost to the NHS of these products is greater than the comparable cost in the supermarkets and therefore it is a condition management that should be considered.<br>Barnsley CCG is currently looking into reviewing the supply |

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| | | | | | | of gluten free foods from the NHS and would gladly input into this engagement exercise. |
| 33 | 4.5 | British Specialist Nutrition Association | Additional developmental areas of emergent practice | It is highly important to acknowledge that there are alternative care pathways, such as pharmacy-led supply models. For example, there was unanimous agreement within the Scottish Government that not only should the trial of the Gluten Free Food Service (GFFS) be retained but also expanded to improve patient access and care. | Alternative supply models for the prescribing of gluten-free foods, such as pharmacy-led supply, offer a means of improving service quality, patient experience, as well as helping to contain costs. Such schemes also support patients to effectively self-manage their long-term condition.<br>The pilot scheme has received widespread support from patients, pharmacists and GPs, with 85% of GPs saying the GFFS had reduced their workload, as well as the number of visits to GP surgeries. The scheme has fostered an improved multidisciplinary working relationship between dietetics and pharmacy, as well as initiating a strong clinician-patient relationship, with 83% of patients switching from getting their prescription from a GP to their community pharmacy | Please see the Scottish Government review of the gluten-free additional pharmaceutical service here. http://www.gov.scot/Publications/2015/09/4234/downloads |
| 34 | 4.5 | British Association of Dermatologists | Key area for quality improvement 2<br>**Optimisation of** | | | |

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| | | | **food labelling** | | | |
| 35 | 4.5 | British Association of Dermatologists | Key area for quality improvement 1 **Addressing of cutaneous symptoms** | | | |
| 36 | | NHS England | Thank you for the opportunity to comment on the above engagement exercise. I wish to confirm that NHS England has no substantive comments to make regarding this quality standard. | | | |
| 37 | | The Royal College of Paediatrics and Child Health | Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the NICE quality standard topic engagement exercise for coeliac disease. We have not received any responses for this consultation.<br>I would be grateful | | | |

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| | | | if you could please acknowledge receipt. | | | |
| 38 | | RCN | This is to inform you that the Royal College of Nursing has no comments to inform on the above quality standard topic engagement at this time.<br>Thank you for the opportunity, we look forward to participating in the next stage. | | | |