NICE National Institute for Health and Care Excellence

Appendix B: Stakeholder consultation comments table

2019 surveillance of Coeliac disease: recognition, assessment and management (2015)

Consultation dates: 9am, Wednesday 23 October to 5pm, Tuesday 5 November 2019

1. Do you agree with the proposal to not update the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Sandwell and West Birmingham NHS Trust	No	The current guideline on screening for Children and Young people with Type 1 diabetes should be changed to reflect new evidence and other international guideline . It should read that they should be screened at diagnosis, at 2 years and 5 years . This is because 85% of CYP with coeliac are asymptomatic at diagnosis and evidence suggests that if you rely on symptoms they can be missed. references 1. Anna Pham-Short, Kim C. Donaghue, Geoffrey Ambler et al . Screening for Celiac Disease in Type 1	Thank you for your comments. NICE guideline NG20 recommends (1.1.1) offering serological testing for CD to people with type 1 diabetes, at diagnosis. It further recommends (1.1.6) advising 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. Recommendation 1.3.4 further advises that healthcare professionals should have a low threshold for re-testing people identified in

Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees

		Diabetes: A Systematic Review. Pediatrics; June 15, 2015;. DOI: 10.1542/peds.2014-2883 2. Anna Pham-Short, Kim C. Donaghue, Geoffrey Ambler, Julie Briody, Sarah Garnett, Craig F. Munns and Maria E. Craig, Abnormal Cortical and Trabecular Bone in Youth With Type 1 Diabetes and Celiac Disease, Diabetes Care, 10.2337/dc18-2376, 42, 8, (1489-1495), (2019 The guideline should comment on the fact that a significant number of symptomatic children are diagnosed based on serology and HLA subtype and not on endoscopic biopsy. There should be guidance on how often Dexa scans and monitoring for complications of coeliac disease should be performed in CYP	recommendation 1.1.1, including those with type 1 diabetes, if they develop any symptoms consistent with coeliac disease. Since this advice allows for subsequent testing of children and young people who are asymptomatic at diagnosis of type 1 diabetes, no impact on the guideline is anticipated. Thank you for citing two studies. The first reference you have cited is included in the evidence summary. The second study was not included in the evidence summary due to indirectness to the review question. The findings from both studies are considered to be consistent with the advice in recommendation 1.1.6. **Diagnosis of coeliac disease in children** NICE guideline NG20 recommendation 1.3.2 covers referral of children for further specialist investigation following serological results, which allows for alternative confirmatory diagnosis to biopsy in certain circumstances. These alternatives could include a non-biopsy approach by using an IgA EMA test to confirm serological positivity or using genetic testing. We acknowledge that a non-biopsy approach could avoid risks and costs of endoscopy for a significant proportion of children with suspected CD, and therefore we will revisit this section of the guideline when the British Society of Gastroenterology publishes its in-progress guidance in this area. **DEXA scans and monitoring for complications** Recommendation 1.4.4 advises that the GP or consultant should assess 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.

			We found no new evidence to inform the frequency of offering DEXA scans or monitoring for complications of coeliac disease.
British Society of Gastroenterology (BSG)	No	**Rare Disease Collaborative Network** An update to the section on non responsive and refractory coeliac disease is required as a Rare Disease Collaborative Network (RDCN) on refractory coeliac disease has been recognised by NHS England. The RDCN provides a much needed national pathway for patients with refractory coeliac disease and will improve diagnosis and treatment for this rare disease. The NICE guideline should signpost clinicians to this network to increase awareness of the Network and to support the diagnosis and management of patients with refractory coeliac disease. The RDCN has published a clinical overview of management of patients with ongoing symptoms, including an algorithm for investigations (Baggus et al. 2019). Importantly, the publication also suggests contact with the RDCN for coordination and optimisation of care for their patients and provides contact details for clinical support. Based on the current NICE guideline, clinicians would be unaware of this support and therefore patients will not have access to this specialist care. Without access to specialist support, there may be an over diagnosis of RCD type 2. An incorrect diagnosis of RCD type 2 would be life changing for patients who would be incorrectly given a poor prognosis with around a 50%	**Rare Disease Collaborative Network** Thank you for highlighting the RDCN pathway. Care pathways are not included in NICE guidelines but could be considered for inclusion in the tools and resources section of the guideline web page. The RDCN could be considered for submission as a NICE shared learning case study via the shared learning submission page. For information, a relevant example shared learning case study is Service Evaluation for Group Clinics for New Patients with newly Diagnosed Coeliac Disease **Diagnosis of coeliac disease in children** Thank you for highlighting the ESPGHAN guidelines in this area. We have acknowledged the updated guidelines in the summary of evidence. Thank you for the studies you submitted. This evidence includes the study you cite by Wolf et al., which will be added to the summary of evidence, and the study by Werksetter et al. which is already included in the summary of evidence. The guideline reports cited by Husby et al. and Paul et al. did not meet the study design inclusion criteria for the surveillance review, however, we acknowledge these guidelines and the content. NICE guideline NG20 recommendation 1.3.2 covers referral of children for further specialist investigation following serological results, which allows for alternative confirmatory diagnosis to biopsy in certain circumstances. These alternatives could include a non-biopsy approach by using an IgA EMA test to confirm serological positivity or using genetic testing.

		five year survival and increased risk of progression to enteropathy associated T cell lymphoma (EATL). Baggus, E.M.R., et al., *How to manage adult coeliac disease: perspective from the NHS England Rare Diseases Collaborative Network for Non-Responsive and Refractory Coeliac Disease.* Frontline Gastroenterology, 2019: p. flgastro-2019-101191 **Diagnosis of coeliac disease in children** Since the publication of NG20, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) has published updated guidance on the diagnosis of coeliac disease (Husby et al. 2019). The new guidance updates the algorithm for the no-biopsy approach for children with antibody levels greater than ten times the upper limit of normal for the assay. An update to the NICE guideline is warranted to align recommendations, particularly with regard to two key changes. The first change is that genetic testing is no longer required for a no-biopsy diagnosis. The second key change is that the no-biopsy approach can be offered to asymptomatic children. The NICE surveillance review acknowledges that HLA DQ2/DQ8 genotyping is relatively expensive. Therefore an	We acknowledge that a non-biopsy approach could avoid risks and costs of endoscopy for a significant proportion of children with suspected CD, and therefore we will revisit this section of the guideline once the British Society of Gastroenterology publishes its in-progress guidance in this area. Regarding the finding that genetic testing is no longer required for a non-biopsy diagnosis, NICE guideline NG20 already advises against human leukocyte antigen (HLA) DQ2 (DQ2.2 and DQ2.5)/DQ8 testing in the initial diagnosis of coeliac disease in non-specialist settings in recommendation 1.2.5. It further advises consideration of this genetic testing only in certain circumstances, without advising this as essential to diagnosis. **Role of the dietitian** The role of the dietitian is outlined in NICE guideline NG20 recommendations 1.5.1 and 1.6.2 which include referral to and information on specialist dietitians. There is also a research recommendation in this area which remains ongoing: How can the role of the dietitian contribute most effectively within a coeliac disease team? We did not identify any new evidence in the surveillance review to address this research recommendation. No impact is anticipated on existing recommendations until strong evidence indicates otherwise. The references you cite by Trott et al. and by Nelson et al. are a conference abstract and survey, respectively, and do not meet the surveillance eligibility criteria. No eligible evidence was identified on group education, but further evidence will be considered at the next surveillance review of this guideline. **Guideline implementation**

		update to bring the diagnosis guidelines for children in line with ESPGHAN could lead to savings for the NHS and also has the potential to reduce the delay to diagnosis. Current NICE guidance for the diagnosis of children is vague and is covered within a footnote which states that "Further investigation may include, but is not limited to, one or more of the following: an IgA EMA test to confirm serological positivity, HLA genetic testing, an endoscopic biopsy". NICE guidance does not signpost to ESPGHAN or BSPGHAN guidance for more detailed information on when each test would be appropriate. Further detail on diagnosis is provided by ESPGHAN, however even several years after publication, there is evidence of poor awareness of the 2012 guidelines among general paediatricians. A survey of consultant general paediatricians found that only 17/100 were able to state all four criteria for a no-biopsy diagnosis from the 2012 ESPGHAN guidelines (Paul et al, 2019). More detailed information from NICE around the diagnosis of coeliac disease in children, or clear signposting to ESPGHAN/BSPGHAN guidance is likely to help improve awareness among general paediatricians. Husby, S., et al., European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for	Thank you for highlighting that more work is needed to support implementation of the guideline to reduce the number of misdiagnoses of irritable bowel syndrome in people with coeliac disease. Although the evidence you submitted was not eligible for the surveillance review, this issue will be passed on to the NICE system support for implementation team for consideration. **Down Syndrome** Thank you for highlighting evidence indicating that DQ typing allowed 47.7% of people with Down's syndrome to be excluded from further testing for coeliac disease. The evidence you submitted is a conference abstract and as such does not meet the eligibility criteria for the surveillance process. However, any new eligible research in this area will be considered at the next surveillance review. The current recommendations to consider testing for coeliac disease in people with Down's syndrome remain valid until new evidence indicates otherwise. **Adult diagnosis with no-biopsy** Thank you for the points raised about the non-biopsy approach to diagnosis in adults. Since the collective evidence does not indicate sufficient diagnostic accuracy of non-biopsy diagnosis in adults to justify a change to the recommendations, no impact on the guideline is anticipated. The study you submitted by Fuchs et al. did not meet the surveillance eligibility criteria. However, we recognise that this is a rapidly evolving area of research and further evidence will be considered when available. We will revisit this section of the guideline when the British Society of Gastroenterology publishes its in-progress guidance in this area.

		Diagnosing Coeliac Disease 2020. J Pediatr Gastroenterol Nutr, 2019 Paul, S.P., et al., Interpretation and implementation of the revised European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) guidelines on pediatric celiac disease amongst consultant general pediatricians in Southwest of England. Indian J Gastroenterol, 2019. 38(3): p. 203-210 **Role of the dietitian** A survey of provision of dietetic services for coeliac disease in the UK has previously identified the level of provision to be at around one-third of the level required (Nelson et al 2007). NG20 also recognised this in the 2015 guideline by stating that "access to specialist dietetic support is currently patchy in the UK". We are anticipating the publication of new research to provide a more recent indication of the current level of provision. Between November 2017 and October 2018 Coeliac UK surveyed n=7244 members diagnosed with coeliac disease and preliminary analysis (data not yet published) shows that: • 19% of people diagnosed with coeliac disease did not see a dietitian within the first 12 months of diagnosis • 48% of people waited over 6 weeks to see a dietitian after diagnosis	**Measuring Adherence** The issue of inappropriate testing for a person who is not eating gluten is addressed in recommendation 1.1.3. In developing the guideline, the committee assessed the utility of serological testing to monitor adherence to the gluten free diet. They reviewed low quality evidence which showed variable sensitivity of serological testing to accurately reflect patient dietary adherence. The committee also noted that in their clinical experience serological testing may inaccurately indicate non-adherence when patients have had a dietitian verify that they have ceased all gluten ingestion. For this reason, the committee wished to highlight that serological testing should not be used alone to measure adherence. In terms of annual monitoring, the evidence identified in the guideline for routine monitoring was of very low quality. This is because although it is possible to design a randomised controlled trial comparing two different monitoring strategies, no such study was identified and only lower quality evidence with design limitations was identified. Further to this, the current surveillance review did not identify any new eligible evidence to signal any impact on the current advice for annual review to assess adherence to a gluten free diet. With regard to your comment on the lack of guidance on serology as a marker for persistent villous atrophy, new evidence indicated that tests for serum tTG IgA and EMA IgA levels had low accuracy in monitoring CD patients for persistent villous atrophy. The evidence suggested that in the absence of these markers, signs and symptoms for this complication should be assessed at annual review and onward referral should be considered if concerns arise. This is consistent with recommendation 1.4.4 for assessing the risk of long-term complications or comorbidities.

		• Only 45% of people with coeliac disease received information about how to read food labels from a healthcare professional in the first year following diagnosis A comparison between group dietetic clinics and individual appointments for newly diagnosed coeliac disease patients has shown group clinics to be resource saving while meeting the expectations of patients and improving understanding of coeliac disease (Trott et al 2016). Group clinics are highlighted under NICE's shared learning database but are not featured within the NICE guideline. An update to include recommendations around group education is warranted as they have the potential to reduce waiting times for patients and also to reduce the dietetic resource required. Nelson, M., et al. *A survey of provision of dietetic services for coeliac disease in the UK* The British Dietetic Association 2007. 20 Trott, N., et al., Comparing dietitian-led group clinics to individual appointments for newly diagnosed patients with coeliac disease (abstract) Gut, 2016. 65(1):A1–A310. **Implementation** There is evidence that the recommendations in the guideline are not being followed in clinical practice. This is particularly true around the diagnosis of coeliac disease. Research published in 2019 has shown no significant change in the duration of symptoms before diagnosis	**Folic acid** No evidence was identified to substantiate the Clinical Knowledge Summary (CKS) advice for high-dose folic acid supplementation (5 mg once daily) for women with CD who are pregnant, or who are planning a pregnancy. CKS must not differ from NICE guidance on matters where NICE guidance exists but can use its own methods to produce additional advice on other matters. CKS does not constitute formal NICE guidance, and until evidence indicates otherwise, no impact on the guideline is anticipated. The CKS advice will be amended to align with NICE guideline NG20. NICE's guideline on maternal and child nutrition provides further advice in this area. **Measurement of total IgA** Thank you for highlighting that testing for total IgA is not always automatically carried out and that in some cases healthcare professionals would have to request total IgA separately and therefore total IgA may not be measured. We did not identify any evidence in the surveillance review to signal an impact on recommendations for serology testing but we will pass this information on to the NICE system support for implementation team for consideration. **Guidance when EMA not available** Thank you for highlighting the implementation issue concerning access to EMA for health professionals in primary and secondary care. We will pass this anecdotal information on to the NICE system support for implementation team to investigate further. **Point of care testing - Simtomax**

		between 2006 and 2015 (Violato et al, 2019). People with coeliac disease are still on average experiencing symptoms for 13 years prior to diagnosis (Violato et al, 2019). In 2013 it was reported that one in four people with coeliac disease have been previously treated for irritable bowel syndrome (IBS) (Card et al, 2013). Research published in 2019 shows that this remains unchanged (West et al, 2019). This is despite the recommendations in both NICE guidelines for coeliac disease (NG20) and irritable bowel syndrome (CG61) that coeliac disease is excluded before a diagnosis of IBS is made. More work is needed to support implementation of the guideline to reduce the number of misdiagnoses of IBS in people with coeliac disease. Coeliac UK are in the process of commissioning epidemiology research which will provide the incidence and prevalence of these conditions in the UK as of 2019, with detail around age, gender, ethnicity, geographical region and socioeconomic status. Information on prior diagnosis of IBS will also be available. Preliminary prevalence figures are anticipated by May 2020. This research will help to identify key areas of under diagnosis. **Down's syndrome** A specific area around diagnosis considered in the NICE surveillance review is the evidence around strengthening the recommendation for coeliac disease testing in people with Down's syndrome. The review did not assess research which has found DQ typing to be effective in coeliac disease screening in children and young people with Down's syndrome. DQ typing within this population	Thank you for highlighting that Simtomax point of care tests for coeliac disease are no longer being manufactured. This will be noted in the surveillance summary of evidence.

		allowed 47.7% people with Down's syndrome to be excluded from further testing for coeliac disease (Sumner et al 2016). Violato, M. and Gray, A. (2019) "The impact of diagnosis on health-related quality of life in people with coeliac disease: a UK population-based longitudinal perspective," BMC Gastroenterology. Springer Science and Business Media LLC, 19(1). doi: 10.1186/s12876-019-0980-6. Card, T. R. et al. (2013) "An excess of prior irritable bowel syndrome diagnoses or treatments in Celiac disease: evidence of diagnostic delay," Scandinavian Journal of Gastroenterology. Informa UK Limited, 48(7), pp. 801–807. doi: 10.3109/00365521.2013.786130. West, J. et al. (2019) "Changes in Testing for and Incidence of Celiac Disease in the United Kingdom," Epidemiology. Ovid Technologies (Wolters Kluwer Health), 30(4), pp. e23–e24. doi: 10.1097/ede.0000000000001006. Sumner, C., et al., *DQ typing is effective in coeliac disease screening in children and young people with down syndrome in south east scotland (abstract).* archdischild 2016;101(Suppl 1):A1–A374 **Adult diagnosis with no-biopsy** NG20 currently recommends that adults with a positive serological test are referred for an endoscopic intestinal biopsy to confirm or exclude coeliac disease.	

		The surveillance review impact statement refers to the British Society for Gastroenterology guidelines. These guidelines were published in 2014, prior to much of the evidence which has now been published around the use of a no-biopsy strategy in adults. There is an evolving debate as to whether coeliac disease can be diagnosed without a biopsy in adults. In Finland, national guidelines permit a no-biopsy diagnosis for adults under certain criteria. Even with these guidelines, endoscopic intestinal biopsy will continue to have an important role in diagnosis for both adults and children as not all patients will meet the criteria for a no-biopsy diagnosis. The NICE surveillance review does not consider the publication by Fuchs et al (2019) which evaluated a no-biopsy diagnosis strategy among three groups with different pre-test probabilities. Using the criteria of tTG antibodies >10 times the upper limit of normal, positive EMA and a positive genetic test, 33% patients could have avoided a biopsy. We are also aware that a prospective study investigating a no-biopsy approach in adults is underway. This is a rapidly evolving area of research and it is important that the research is reflected in guidance from NICE. There is currently no acknowledgement from NICE around the emerging evidence of a no-biopsy strategy for the diagnosis of coeliac disease in adults. A statement from NICE on the current debate as to whether adult coeliac disease can be diagnosed using a no-biopsy strategy is	

		warranted. It is important that NICE provides a statement on this approach as anecdotal evidence suggests that a no-biopsy approach is already being introduced in some cases. Fuchs, V., et al., Serology-based criteria for adult coeliac disease have excellent accuracy across the range of pre-test probabilities. Aliment Pharmacol Ther, 2019. 49(3): p. 277-284. **Measuring adherence** The surveillance review refers to discussions among the guideline committee around the utility of serological testing to monitor adherence to the gluten free diet. The review also references a meta-analysis which demonstrates a low sensitivity (less than 50%) of serum tTG IgA and EMA IgA in detection of persistent villous atrophy. The current NICE guideline recommends that during annual review healthcare professionals should consider the need for adherence to the gluten free diet. There is no further information within the guideline on how adherence should, or should not be assessed. There is currently no reference to the use of serology to measure adherence to the diet, or as a marker of persistent villous atrophy within the NICE guideline. The only reference features in the full NICE guideline. It is unlikely that healthcare professionals who do not specialise in coeliac disease will read the full NICE guideline and therefore an update to the summary guideline to highlight this evidence and best practice from the guideline committee will help to raise awareness of the low	

		sensitivity of serum tTG IgA and EMA IgA in detection of persistent villous atrophy. **Folic acid** The NICE clinical knowledge summary (CKS) recommends 5 mg folic acid supplementation for women during pre-conception and pregnancy. We believe that this should be reflected in the NICE guideline for consistency. The NICE surveillance review states that no evidence was identified to substantiate this advice and therefore no impact on the guideline is anticipated. It states that the CKS is based on expert opinion. CKS's are featured on the NICE website which implies endorsement by NICE. The NICE surveillance review has not identified any evidence to substantiate this advice and is also not seeking consistency between the guideline and CKS. The basis for this recommendation is as a precaution in case of ongoing malabsorption. **Measurement of total IgA** NICE guidelines recommend testing for total IgA and IgA tTG as the first choice serological test. From conversations with healthcare professionals we are aware that the request to test for total IgA is not always automatically carried out. In some cases healthcare professionals would have to request total IgA separately and therefore total IgA may not be measured. We are aware that this is not documented in published research and is anecdotal information, but it has important implications for diagnosis and it is important that NICE are aware of this to be able to investigate further.	

		Guidance when EMA not available NG20 recommends using IgA endomysial antibodies (EMA) if IgA tTG is weakly positive. In addition, ESPGHAN guidelines recommend the use of EMA in a second blood sample as part of the no-biopsy strategy for diagnosis of coeliac disease. We are aware that some healthcare professionals, including some secondary care settings do not have access to EMA. As with the point above around measurement of total IgA, this is not documented in published research and is anecdotal information but is important for surveillance around implementation of the guideline. Pragmatic guidance from NICE for these settings would be useful for healthcare professionals. **Point of care testing - Simtomax** The impact statement on point of care testing states that there is some evidence to support the use of Simtomax in diagnosing coeliac disease in primary care. Unfortunately, Simtomax point of care tests for coeliac disease are no longer being manufactured.	
Royal College of Physicians	No	The RCP endorse the response submitted by the BSG.	Thank you for your comment. Please refer to the response to the BSG comments for information on the points raised.
Diabetes UK	No	Two key areas of the guideline surrounding coeliac disease are out of date and we suggest that these require amending.	Thank you for your comment. It is not clear from your comment which two areas of the guideline you consider to be out of date. The surveillance review considered eligible evidence which published since the guideline search; we did not consider this new evidence to

			indicate that an update is needed. Further emerging evidence will be considered at the next surveillance review.
Coeliac UK	No	**Rare Disease Collaborative Network** An update to the section on non responsive and refractory coeliac disease is required as a Rare Disease Collaborative Network (RDCN) on refractory coeliac disease has been recognised by NHS England. The RDCN provides a much needed national pathway for patients with non responsive or refractory coeliac disease and will improve diagnosis and treatment for this rare condition. The NICE guideline should signpost clinicians to this network to increase awareness of the Network and to support the diagnosis and management of patients with refractory coeliac disease. The RDCN has published a clinical overview of management of patients with ongoing symptoms, including an algorithm for investigations (Baggus et al. 2019). Importantly, the publication also suggests contact with the RDCN for support with diagnosis (flow cytometry analysis, which is not available outside the RDCN, as clonality testing alone is insufficient) coordination and optimisation of care for their patients and provides contact details for clinical support. Based on the current NICE guideline, clinicians would be unaware of this support and therefore patients will not have access to this specialist care. Without access to specialist support, there may be an over diagnosis of RCD type 2. An incorrect diagnosis of RCD type 2 would be life changing for patients who would be incorrectly given a poor prognosis with around a 50% five year survival and increased risk of	**Rare Disease Collaborative Network** Thank you for highlighting the RDCN pathway. Care pathways are not included in NICE guidelines but could be considered for inclusion in the tools and resources section of the guideline web page. The RDCN could be considered for submission as a NICE shared learning case study via the shared learning submission page. For information, a relevant example shared learning case study is Service Evaluation for Group Clinics for New Patients with newly Diagnosed Coeliac Disease **Diagnosis of coeliac disease in children** Thank you for highlighting the ESPGHAN guidelines in this area. We have acknowledged the updated guidelines in the summary of evidence. Thank you for the studies you submitted. This evidence includes the study you cite by Wolf et al., which will be added to the summary of evidence, and the study by Werksetter et al. which is already included in the summary of evidence. The guideline reports cited by Husby et al. and Paul et al. did not meet the study design inclusion criteria for the surveillance review, however, we acknowledge these guidelines and the content. NICE guideline NG20 recommendation 1.3.2 covers referral of children for further specialist investigation following serological results, which allows for alternative confirmatory diagnosis to biopsy in certain circumstances. These alternatives could include a non-biopsy approach by using an IgA EMA test to confirm serological positivity or using genetic testing.

		progression to enteropathy associated T cell lymphoma (EATL). Baggus, E.M.R., et al., *How to manage adult coeliac disease: perspective from the NHS England Rare Diseases Collaborative Network for Non-Responsive and Refractory Coeliac Disease.* Frontline Gastroenterology, 2019: p. flgastro-2019-101191 **Diagnosis of coeliac disease in children** Since the publication of NG20, the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) has published updated guidance on the diagnosis of coeliac disease (Husby et al. 2019). The new guidance updates the algorithm for the no-biopsy approach for children with antibody levels greater than ten times the upper limit of normal for the assay. An update to the NICE guideline is warranted to align recommendations, particularly with regard to two key changes. The first change is that genetic testing is no longer required for a no-biopsy diagnosis. The second key change is that the no-biopsy approach can be offered to asymptomatic children. The NICE surveillance review acknowledges that HLA DQ2/DQ8 genotyping is relatively expensive. Therefore an update to bring the diagnosis guidelines for children in line with ESPGHAN could lead to savings for the NHS and also has the potential to reduce the delay to diagnosis.	We acknowledge that a non-biopsy approach could avoid risks and costs of endoscopy for a significant proportion of children with suspected CD, and therefore we will revisit this section of the guideline once the British Society of Gastroenterology publishes its in-progress guidance in this area. Regarding the finding that genetic testing is no longer required for a non-biopsy diagnosis, NICE guideline NG20 already advises against human leukocyte antigen (HLA) DQ2 (DQ2.2 and DQ2.5)/DQ8 testing in the initial diagnosis of coeliac disease in non-specialist settings in recommendation 1.2.5. It further advises consideration of this genetic testing only in certain circumstances, without advising this as essential to diagnosis. **Role of the dietitian** The role of the dietitian is outlined in NICE guideline NG20 recommendations 1.5.1 and 1.6.2 which include referral to and information on specialist dietitians. There is also a research recommendation in this area which remains ongoing: How can the role of the dietitian contribute most effectively within a coeliac disease team? We did not identify any new evidence in the surveillance review to address this research recommendation. No impact is anticipated on existing recommendations until strong evidence indicates otherwise. The references you cite by Trott et al. and by Nelson et al. are a conference abstract and survey, respectively, and do not meet the surveillance eligibility criteria. No eligible evidence was identified on group education, but further evidence will be considered at the next surveillance review of this guideline. **Guideline implementation**

		Current NICE guidance for the diagnosis of children is vague and is covered within a footnote which states that "Further investigation may include, but is not limited to, one or more of the following: an IgA EMA test to confirm serological positivity, HLA genetic testing, an endoscopic biopsy". NICE guidance does not signpost to ESPGHAN or BSPGHAN guidance for more detailed information on when each test would be appropriate. Further detail on diagnosis is provided by ESPGHAN, however even several years after publication, there is evidence of poor awareness of the 2012 guidelines among general paediatricians. A survey of consultant general paediatricians found that only 17/100 were able to state all four criteria for a no-biopsy diagnosis from the 2012 ESPGHAN guidelines (Paul et al, 2019). More detailed information from NICE around the diagnosis of coeliac disease in children, or clear signposting to ESPGHAN/BSPGHAN guidance is likely to help improve awareness among general paediatricians. Husby, S., et al., European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Coeliac Disease 2020. J Pediatr Gastroenterol Nutr, 2019 Paul, S.P., et al., Interpretation and implementation of the revised European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) guidelines on pediatric celiac disease	Thank you for highlighting that more work is needed to support implementation of the guideline to reduce the number of misdiagnoses of irritable bowel syndrome in people with coeliac disease. Although the evidence you submitted was not eligible for the surveillance review, this issue will be passed on to the NICE system support for implementation team for consideration. **Down Syndrome** Thank you for highlighting evidence indicating that DQ typing allowed 47.7% of people with Down's syndrome to be excluded from further testing for coeliac disease. The evidence you submitted is a conference abstract and as such does not meet the eligibility criteria for the surveillance process. However, any new eligible research in this area will be considered at the next surveillance review. The current recommendations to consider testing for coeliac disease in people with Down's syndrome remain valid until new evidence indicates otherwise. **Adult diagnosis with no-biopsy** Thank you for the points raised about the non-biopsy approach to diagnosis in adults. Since the collective evidence does not indicate sufficient diagnostic accuracy of non-biopsy diagnosis in adults to justify a change to the recommendations, no impact on the guideline is anticipated. The study you submitted by Fuchs et al. did not meet the surveillance eligibility criteria. However, we recognise that this is a rapidly evolving area of research and further evidence will be considered when available. We will revisit this section of the guideline when the British Society of Gastroenterology publishes its in-progress guidance in this area.

		amongst consultant general pediatricians in Southwest of England. Indian J Gastroenterol, 2019. 38(3): p. 203-210 **Role of the dietitian** A survey of provision of dietetic services for coeliac disease in the UK has previously identified the level of provision to be at around one-third of the level required (Nelson et al 2007). NG20 also recognised this in the 2015 guideline by stating that "access to specialist dietetic support is currently patchy in the UK". We are anticipating the publication of new research to provide a more recent indication of the current level of provision. Between November 2017 and October 2018 Coeliac UK surveyed n=7244 members diagnosed with coeliac disease and preliminary analysis (manuscript in writing) shows that: • 19% of people diagnosed with coeliac disease did not see a dietitian within the first 12 months of diagnosis • 48% of people waited over 6 weeks to see a dietitian after diagnosis • Only 45% of people with coeliac disease received information about how to read food labels from a healthcare professional in the first year following diagnosis A comparison between group dietetic clinics and individual appointments for newly diagnosed coeliac disease patients has shown group clinics to be resource saving while	**Measuring Adherence** The issue of inappropriate testing for a person who is not eating gluten is addressed in recommendation 1.1.3. In developing the guideline, the committee assessed the utility of serological testing to monitor adherence to the gluten free diet. They reviewed low quality evidence which showed variable sensitivity of serological testing to accurately reflect patient dietary adherence. The committee also noted that in their clinical experience serological testing may inaccurately indicate non-adherence when patients have had a dietitian verify that they have ceased all gluten ingestion. For this reason, the committee wished to highlight that serological testing should not be used alone to measure adherence. In terms of annual monitoring, the evidence identified in the guideline for routine monitoring was of very low quality. This is because although it is possible to design a randomised controlled trial comparing two different monitoring strategies, no such study was identified and only lower quality evidence with design limitations was identified. Further to this, the current surveillance review did not identify any new eligible evidence to signal any impact on the current advice for annual review to assess adherence to a gluten free diet. With regard to your comment on the lack of guidance on serology as a marker for persistent villous atrophy, new evidence indicated that tests for serum tTG IgA and EMA IgA levels had low accuracy in monitoring CD patients for persistent villous atrophy. The evidence suggested that in the absence of these markers, signs and symptoms for this complication should be assessed at annual review and onward referral should be considered if concerns arise. This is consistent with recommendation 1.4.4 for assessing the risk of long-term complications or comorbidities.

		meeting the expectations of patients and improving understanding of coeliac disease (Trott et al. 2016). Group clinics are highlighted under NICE's shared learning database but are not featured within the NICE guideline. An update to include recommendations around group education is warranted as they have the potential to reduce waiting times for patients and also to reduce the dietetic resource required. Nelson, M., et al. *A survey of provision of dietetic services for coeliac disease in the UK* The British Dietetic Association 2007. 20 Trott, N., et al., Comparing dietitian-led group clinics to individual appointments for newly diagnosed patients with coeliac disease (abstract) Gut, 2016. 65(1):A1–A310. There is evidence that the recommendations in the guideline are not being followed in clinical practice. This is particularly true around the diagnosis of coeliac disease. Research published in 2019 has shown no significant change in the duration of symptoms before diagnosis between 2006 and 2015 (Violato et al, 2019). People with coeliac disease are still on average experiencing symptoms for 13 years prior to diagnosis (Violato et al, 2019). In 2013 it was reported that one in four people with coeliac disease have been previously treated for irritable bowel syndrome (IBS) (Card et al. 2013). Research published in 2019 shows that this remains unchanged (West et al. 2019). This is despite the recommendations in both NICE	**Folic acid** No evidence was identified to substantiate the Clinical Knowledge Summary (CKS) advice for high-dose folic acid supplementation (5 mg once daily) for women with CD who are pregnant, or who are planning a pregnancy. CKS must not differ from NICE guidance on matters where NICE guidance exists but can use its own methods to produce additional advice on other matters. CKS does not constitute formal NICE guidance, and until evidence indicates otherwise, no impact on the guideline is anticipated. The CKS advice will be amended to align with NICE guideline NG20. NICE's guideline on maternal and child nutrition provides further advice in this area. **Measurement of total IgA** Thank you for highlighting that testing for total IgA is not always automatically carried out and that in some cases healthcare professionals would have to request total IgA separately and therefore total IgA may not be measured. We did not identify any evidence in the surveillance review to signal an impact on recommendations for serology testing but we will pass this information on to the NICE system support for implementation team for consideration. **Guidance when EMA not available** Thank you for highlighting the implementation issue concerning access to EMA for health professionals in primary and secondary care. We will pass this anecdotal information on to the NICE system support for implementation team to investigate further. **Point of care testing - Simtomax**

		guidelines for coeliac disease (NG20) and irritable bowel syndrome (CG61) that coeliac disease is excluded before a diagnosis of IBS is made. More work is needed to support implementation of the guideline to reduce the number of misdiagnoses of IBS in people with coeliac disease. Coeliac UK are in the process of commissioning epidemiology research which will provide the incidence and prevalence of these conditions in the UK as of 2019, with detail around age, gender, ethnicity, geographical region and socioeconomic status. Information on prior diagnosis of IBS will also be available. Preliminary prevalence figures are anticipated by May 2020. This research will help to identify key areas of under diagnosis. A specific area around diagnosis considered in the NICE surveillance review is the evidence around strengthening the recommendation for coeliac disease testing in people with Down's syndrome. The review did not assess research which has found DQ typing to be effective in coeliac disease screening in children and young people with Down's syndrome. DQ typing within this population allowed 47.7% people with Down's syndrome to be excluded from further testing for coeliac disease (Sumner et al. 2016). Violato, M. and Gray, A. (2019) "The impact of diagnosis on health-related quality of life in people with coeliac disease: a UK population-based longitudinal perspective," BMC	Thank you for highlighting that Simtomax point of care tests for coeliac disease are no longer being manufactured. This will be noted in the surveillance summary of evidence.

		Gastroenterology. Springer Science and Business Media LLC, 19(1). doi: 10.1186/s12876-019-0980-6. Card, T. R. et al. (2013) "An excess of prior irritable bowel syndrome diagnoses or treatments in Celiac disease: evidence of diagnostic delay," Scandinavian Journal of Gastroenterology. Informa UK Limited, 48(7), pp. 801–807. doi: 10.3109/00365521.2013.786130. West, J. et al. (2019) "Changes in Testing for and Incidence of Celiac Disease in the United Kingdom," Epidemiology. Ovid Technologies (Wolters Kluwer Health), 30(4), pp. e23–e24. doi: 10.1097/ede.0000000000001006. Sumner, C., et al., *DQ typing is effective in coeliac disease screening in children and young people with down syndrome in south east scotland (abstract).* archdischild 2016;101(Suppl 1):A1–A374 **Adult diagnosis with no biopsy** NG20 currently recommends that adults with a positive serological test are referred for an endoscopic intestinal biopsy to confirm or exclude coeliac disease. The surveillance review impact statement refers to the British Society for Gastroenterology guidelines. These guidelines were published in 2014, prior to much of the evidence which has now been published around the use of a no-biopsy strategy in adults. There is an evolving debate as to whether coeliac disease can be diagnosed without a biopsy in adults. In Finland, national guidelines permit a no-biopsy diagnosis for adults under certain criteria. Even with these guidelines,	

		endoscopic intestinal biopsy will continue to have an important role in diagnosis for both adults and children as not all patients will meet the criteria for a no-biopsy diagnosis. The NICE surveillance review does not consider the publication by Fuchs et al. (2019) which evaluated a no-biopsy diagnosis strategy among three groups with different pre-test probabilities. Using the criteria of tTG antibodies >10 times the upper limit of normal, positive EMA and a positive genetic test, 33% patients could have avoided a biopsy. We are also aware that a prospective study investigating a no-biopsy approach in adults is underway. This is a rapidly evolving area of research and it is important that the research is reflected in guidance from NICE. There is currently no acknowledgement from NICE around the emerging evidence of a no-biopsy strategy for the diagnosis of coeliac disease in adults. A statement from NICE on the current debate as to whether adult coeliac disease can be diagnosed using a no-biopsy strategy is warranted. It is important that NICE provides a statement on this approach as anecdotal evidence suggests that a no biopsy approach is already being introduced in some cases.	

		Fuchs, V., et al., Serology-based criteria for adult coeliac disease have excellent accuracy across the range of pre-test probabilities. Aliment Pharmacol Ther, 2019. 49(3): p. 277-284. **Measuring adherence** The surveillance review refers to discussions among the guideline committee around the utility of serological testing to monitor adherence to the gluten free diet. The review also references a meta-analysis which demonstrates a low sensitivity (less than 50%) of serum tTG IgA and EMA IgA in detection of persistent villous atrophy. The current NICE guideline recommends that during annual review healthcare professionals should consider the need for adherence to the gluten free diet. There is no further information within the guideline on how adherence should, or should not be assessed. There is currently no reference to the use of serology to measure adherence to the diet, or as a marker of persistent villous atrophy within the NICE guideline. The only reference features in the full NICE guideline. It is unlikely that healthcare professionals who do not specialise in coeliac disease will read the full NICE guideline and therefore an update to the summary guideline to highlight this evidence and best practice from the guideline committee will help to raise awareness of the low sensitivity of serum tTG IgA and EMA IgA in detection of persistent villous atrophy. **Folic acid** The NICE clinical knowledge summary (CKS) recommends 5 mg/day folic acid supplementation for women during	

		pre-conception and pregnancy. We believe that this should be reflected in the NICE guideline for consistency. The NICE surveillance review states that no evidence was identified to substantiate this advice and therefore no impact on the guideline is anticipated. It states that the CKS is based on expert opinion. CKS's are featured on the NICE website which implies endorsement by NICE. The NICE surveillance review has not identified any evidence to substantiate this advice and is also not seeking consistency between the guideline and CKS. The basis for this recommendation is as a precaution in case of ongoing malabsorption. **Measurement of total IgA** NICE guidelines recommend testing for total IgA and IgA tTG as the first choice serological test. From conversations with healthcare professionals we are aware that the request to test for total IgA is not always automatically carried out. In some cases healthcare professionals would have to request total IgA separately and therefore total IgA may not be measured. We are aware that this is not documented in published research and is anecdotal information, but it has important implications for diagnosis and it is important that NICE is aware of this to be able to investigate further. **Guidance when EMA not available**	

		NG20 recommends using IgA endomysial antibodies (EMA) if IgA tTG is weakly positive. In addition, ESPGHAN guidelines recommend the use of EMA in a second blood sample as part of the no-biopsy strategy for diagnosis of coeliac disease. We are aware that some healthcare professionals, including some secondary care settings do not have access to EMA. As with the point above around measurement of total IgA, this is not documented in published research and is anecdotal information but is important for surveillance around implementation of the guideline. Pragmatic guidance from NICE for these settings would be useful for healthcare professionals. **Point of care testing - Simtomax** The impact statement on point of care testing states that there is some evidence to support the use of Simtomax in diagnosing coeliac disease in primary care. Unfortunately, Simtomax point of care tests for coeliac disease are no longer being manufactured.	
Fountain practice, Bourne Hall Health centre	No	I feel it maybe beneficial to look at this, more discharging patients in primary care annual follow up bloods may not occur.	Thank you for your comments. NICE guideline NG20 advises (1.4.3-1.4.4)) offering an annual review to people with coeliac disease and if concerns are raised, to refer the person to a GP or consultant for assessing the need for specific blood tests in addition to other assessments and the need for referral. The surveillance review did

			not identify any evidence to indicate that a change to this advice is warranted.
British Dietetic Association	No	1. Strongly support the inclusion of recommending prescription of gluten free foods (minimum breads and flour mixes) for patients with coeliac disease. Receiving gluten free foods on prescription has been associated with dietary adherence[1]. Receiving gluten free foods on prescription help address inequalities amongst the patient population diagnosed with coeliac disease due to the high cost and minimal availability of gluten free breads and flour mixes in budget stores persisting[2]. 2. The value of the dietitian should be made more prominent, to support patients adhere to the gluten free diet and nutritional adequacy of CD, especially for those with comorbidities.	**Prescription of gluten free foods** The guideline does not make recommendations on prescribing of gluten free foods because policy and legislation in this area is set at a national level by the Department for Health and Social Care, with implementation passed to CCGs at a local and regional level. The prescription of gluten free foods is outside of the scope of this guideline and beyond the remit of NICE. No impact is anticipated on the guideline. **Role of the dietitian** The role of the dietitian is outlined in NICE guideline NG20 recommendations 1.5.1 and 1.6.2 which include referral to and information on specialist dietitians. In view of limited evidence in the area, the guideline also makes a recommendations for research: How can the role of the dietitian contribute most effectively within a coeliac disease team? We did not identify any new evidence in the current surveillance review to address this research recommendation. No impact is anticipated on existing recommendations until strong evidence indicates otherwise.
Royal College of Paediatrics and Child Health	Yes	The reviewer is happy with the decision to not update the guideline.	Thank you for your comment.

Royal Osteoporosis Society	Yes	The overriding view was that there is not a reason to review due to associated bone disease. The feedback is that all newly diagnosed coeliac patients regardless of age and irrespective of other risk factors are referred to osteoporosis services for advice. There are also referrals for repeat DXA scans, even in the presence of a previous normal scan result. The response we have is that people are followed up if they have significantly low BMD It has been suggested to re-word, e.g. replace 'the need for a dual-energy X-ray absorptiometry (DEXA) scan (in line with the NICE guideline) with 'the need for DXA IF OTHER MAJOR RISK FACTORS FOR OSTEOPOROSIS ARE PRESENT (see NICE guideline)'. Perhaps also add that repeat DXA scans (after a minimum of 2 years) should only be considered if the initial DXA shows osteoporosis. It was thought that the guidance is confusing as an example in the inequality section. There is other guidance that people are using for example, 2014 BSG guidance - relevant section below: The risk of osteoporosis144 179–183 and bone fracture184–190 is increased with CD,2 with one Swedish study showing an excess risk of any fracture of 481/100 000 person-years in adults with CD189 and a British study (13% of individuals were children) 320/100 000 person-years.184 The excess risk is reduced with good dietary adherence and reduction in intestinal villous atrophy, and bone density increases during the first year of GFD	Thank you for your comments. We appreciate your agreement with the proposal not to update the guideline. **Dual-energy X-ray absorptiometry (DEXA) scan** Recommendation 1.4.4 advises that the GP or consultant should assess 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. This should include an assessment of other major risk factors for osteoporosis, and whether repeat scans are needed if the initial scan shows osteoporosis. We did not identify any evidence to indicate the need for referral of all newly diagnosed CD patients to osteoporosis services. **Other guidelines** It is recognised that NICE guidance exists alongside other guidance and may differ in some of its recommendations. NICE guideline recommendations are based on the best available evidence. We use a wide range of different types of evidence and other information – from scientific research using a variety of methods, to testimony from practitioners and people using services.

		adherence.191–195 However, one population-based study found a similar excess risk for fractures before and after coeliac diagnosis (eg, the incidence ratio 5–10 years before CD diagnosis was 1.8 compared with 2.2 some 5–10 years after diagnosis).189 On the basis of current evidence, the suggestion should therefore be to measure calcium, alkaline phosphatase and vitamin D levels (and parathyroid hormone for compensatory increase) at diagnosis and replace as necessary. Calcium intake should be maintained at or above 1000 mg per day.196 Bone density should be measured in those at high risk of osteoporosis; appropriate criteria for judging this are given by the BSG (http://www.bsg.org.uk/images/stories/clinical/ost_coe_ibd.pdf). Repeat bone density investigations (generally after an interval of ≥2 years) should otherwise be considered in patients who have low bone density on index measurement following initiation of appropriate treatment, or who have evidence of ongoing villous atrophy or poor dietary adherence. Postmenopausal women with CD may require supplementation in addition to the GFD.197 Loss of bone density at a greater than expected rate should prompt measurement of vitamin D levels, dietary review of adherence, consideration of repeat intestinal mucosal biopsy and review of additional risk factors such as hypogonadism.	
BSPGHAN. British Society of Paediatric Gastroenterology	No	the BSPGHAN coeliac working group on behalf of BSPGHAN does not agree with this proposal and , as you	Thank you for your comments. **Diagnosis of coeliac disease in children**

Hepatology and Nutrition		can see offers more evidence of studies and the new ESPGHAN guidelines in support. We feel it offers a considerable update to NICE NG20 and should at the very least, be updated for paediatric guidance. there are still considerable inequalities in management, both in GF prescriptions and their postcode access issues, and in the commencement of a new national service for RCD now based in sheffield (cambridge). there are also issues flagged up in our comments about management especially the importance of protecting adults from issues relating to pregnancy planning and pneumococcal vaccination. although detailed in other guidance, there needs to be a common repository of advice for management of coeliac patients. in our view this could be done easily in an update and would influence better management of patients with CD. B. In addition to this, DQ typing is now out of the ESPGHAN 2020 (to be called 2020) guidelines. Published ahead of print in October 2019. This should be included in the review. This also addresses the point made by one of your expert reviewers and makes the no-biopsy strategy even easier. Please see link for information. It will be published in print in the January 2020 edition of JPGN. **European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines for Diagnosing Coeliac Disease 2020** Husby, Steffen[*]; Koletzko, Sibylle[†]; Korponay-Szabó, Ilma[‡]; Kurppa, Kalle[§]; Mearin, M. Luisa[‖]; Ribes-Koninckx,	Thank you for highlighting the ESPGHAN guidelines in this area. We have acknowledged this guideline in the evidence summary. It is recognised that NICE guidance exists alongside other guidance and may differ in some of its recommendations. NICE guideline NG20 was developed following an evidence based process as set out in Developing NICE guidelines: the manual and involved the input from a committee of experts and lay members. NICE guideline NG20 recommendation 1.3.2 covers referral of children for further specialist investigation following serological results, which allows for alternative confirmatory diagnosis to biopsy in certain circumstances. These alternatives could include a non-biopsy approach by using an IgA EMA test to confirm serological positivity or using genetic testing. We acknowledge that a non-biopsy approach could avoid risks and costs of endoscopy for a significant proportion of children with suspected CD, and therefore we will revisit this section of the guideline once the British Society of Gastroenterology publishes its in-progress guidance in this area. Regarding the finding that genetic testing is no longer required for a no-biopsy diagnosis, NICE guideline NG20 already advises against HLA DQ2 (DQ2.2 and DQ2.5)/DQ8 testing in the initial diagnosis of coeliac disease in non-specialist settings in recommendation 1.2.5. It further advises consideration of this genetic testing only in certain circumstances, without advising this as essential to diagnosis. **Diagnosis of coeliac disease in adults** Thank you for the points raised about the non-biopsy approach to diagnosis in adults. Since the collective evidence does not indicate sufficient diagnostic accuracy of non-biopsy diagnosis in adults to justify a change to the recommendations, no impact on the guideline

		Carmen[¶]; Shamir, Raanan[#]; Troncone, Riccardo[**]; Auricchio, Renata[**]; Castillejo, Gemma[††]; Christensen, Robin[‡‡]; Dolinsek, Jernej[§§]; Gillett, Peter[‖‖]; Hróbjartsson, Asbjørn[¶¶]; Koltai, Tunde[##]; Maki, Markku[§]; Nielsen, Sabrina Mai[‡‡]; Popp, Alina; Bucharest, [***]; Størdal, Ketil[†††]; Werkstetter, Katharina[†]; Wessels, Margreet[‡‡‡] Journal of Pediatric Gastroenterology and Nutrition: October 17, 2019 - Volume Publish Ahead of Print - Issue - p doi: 10.1097/MPG.0000000000002497 https://journals.lww.com/jpgn/Abstract/publishahead/European_Society_Paediatric_Gastroenterology,.96328.aspx C. please see above comment and see Questions 2 3 4 5 and 6 (this systematically reviewed all relevant studies regarding the cut off value) AND werkstetter calls into question the validity of biopsy as a gold standard due to pathology reporting. D. no-biopsy diagnosis in adults- this paper from Finland was not part of your surveillance review - see Fuchs et al. There is increasingly good evidence that the same strategy is valid in adults across all groups. This paper should be reviewed. I understand that this is perhaps premature in the UK. The Finns have adopted no-biopsy strategy for adults as part of a national guideline. Maybe one day we will do this? It needs to be reviewed and taken into account please. https://www.ncbi.nlm.nih.gov/pubmed/30592070	is anticipated. However, we recognise that this is a rapidly evolving area of research and further evidence will be considered when available. We will revisit this section of the guideline when the British Society of Gastroenterology publishes its in-progress guidance in this area. **Prescription of gluten free foods** The guideline does not make recommendations on prescribing of gluten free foods because policy and legislation in this area is set at a national level by the Department for Health and Social Care, with implementation passed to CCGs at a local and regional level. No impact is anticipated on the guideline. **Folic acid supplementation** No evidence was identified to substantiate the Clinical Knowledge Summary (CKS) advice for high-dose folic acid supplementation (5 mg once daily) for women with CD who are pregnant, or who are planning a pregnancy. CKS must not differ from NICE guidance on matters where NICE guidance exists but can use its own methods to produce additional advice on other matters. CKS does not constitute formal NICE guidance, and until evidence indicates otherwise, no impact on the guideline is anticipated. The CKS advice will be amended to align with NICE guideline NG20. NICE's guideline on maternal and child nutrition provides further advice in this area. **Pneumococcal infection** Thank you for the points raised concerning pneumococcal vaccination and risk of pneumonia.

		Aliment Pharmacol Ther. 2019 Feb;49(3):277-284. doi: 10.1111/apt.15109. Epub 2018 Dec 27. **Serology-based criteria for adult coeliac disease have excellent accuracy across the range of pre-test probabilities.** Fuchs V[1], Kurppa K[2], Huhtala H[3], Laurila K[1], Mäki M[2], Collin P[4], Salmi T[1,5], Luostarinen L[6], Saavalainen P[7], Kaukinen K[1,8]. E.The management of **refractory coeliac disease**. There is a new guidance and a specialised rare disease collaborative network group (Sheffield and Cambridge) now set up to take referrals on a Tertiary basis across the UK. See link . This absolutely neds to be referenced in an update as they are a small but very vulnerable group who have a potentially disastrous outcome. Again an update would reference this new and valuable service to the public, GPs and secondary care teams alike. This is detailed in an excellent review and publicises the team's work and referral mechanisms. Baggus EMR, Hadjivassiliou M, Cross S, *et al* How to manage adult coeliac disease: perspective from the NHS England Rare Diseases Collaborative Network for Non-Responsive and Refractory Coeliac Disease *Frontline Gastroenterology* Published Online First: 08 August 2019. doi: 10.1136/flgastro-2019-101191 https://fg.bmj.com/content/early/2019/08/07/flgastro-2019-101191.info	At the start of the guideline development process NICE held a consultation on the draft scope and a workshop for stakeholder organisations to provide direct feedback. The developers explained that participants at the stakeholder workshop felt that immunisation was not an area of significant controversy and did not need to be specifically mentioned. The consultation comments for the draft guidance showed that that pneumococcal vaccination wasn't mentioned by any of the stakeholders who commented on the draft guidance. As you acknowledged, new evidence identified in the 2019 surveillance review indicates a higher risk of pneumococcal infection for hospitalised people with CD. We note the study by Zingone et al. which will be added to the evidence summary and our conclusion to consider preventive pneumococcal vaccination will apply to community-acquired as well as hospital-acquired pneumonia, in addition to those with functional hyposplenism. However, vaccination guidance is set at a national level by the UK government through the Joint Committee on Vaccination and Immunisation and is not within the scope of NICE guideline NG20. Therefore, no impact on the guideline is anticipated. A cross referral will be added to the guideline to the JCVI guidance on pneumococcal vaccination. **New network on refractory coeliac disease** Thank you for highlighting the RDCN pathway. Care pathways are not included in NICE guidelines but could be considered for inclusion in the tools and resources section of the guideline web page. The RDCN could be considered for submission as a NICE shared learning case study via the shared learning submission page. For information, a relevant example shared learning case study is Service Evaluation for Group Clinics for New Patients with newly Diagnosed Coeliac Disease

2. Do you have any comments on areas excluded from the scope of the guideline?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Quality & Leadership Team – NICE	No	Not answered	Thank you.
Sandwell and West Birmingham NHS Trust	No	Not answered	Thank you.
British Society of Gastroenterology (BSG)	Yes	**Dermatitis herpetiformis** Dermatitis herpetiformis (DH) should be considered within the scope of NG20 as it is the cutaneous manifestation of coeliac disease. Page 4 of the consultation document states that "the guideline committee did not find any evidence (based on criteria outlined in the search protocols) to indicate that testing for the existence of DH would be a reliable indicator of CD". People with DH often do not present with overt gastrointestinal symptoms (Reunala et al, 2018). Therefore, based on the current list of symptoms within NG20 their diagnosis would be missed. Currently the only mention of DH within NG20 is under the "context" heading as an example of a non-gastrointestinal symptom. The clinical features of DH (including appearance and common sites for DH rash) should be included under the symptoms of coeliac disease rather than a diagnosis of DH as those already diagnosed with DH will have initiated a gluten free diet.	Thank you for your comments. **Dermatitis herpetiformis** Thank you for your suggestions for including DH in the guideline recommendations. The research methods and discussion that led to these recommendations are in section 4.1.2 of the full guideline. In terms of the searches, the guideline committee suggested an exhaustive list of clinical signs and symptoms including co-existing conditions, prior to conducting the literature searches for this review question. This list included dermatitis herpetiformis, as you can see in the full list of search protocols (Appendix C). Studies were found linking dermatitis herpetiformis and coeliac disease but these were excluded in accordance with the predefined search protocols (see Appendix F for the full list of excluded studies and reasons for each exclusion). In summary, the review team did not find any evidence meeting the search protocols to indicate that testing for the existence of dermatitis herpetiformis would be a reliable indicator of

		Reunala, T., et al., Dermatitis Herpetiformis: A Common Extraintestinal Manifestation of Coeliac Disease. Nutrients, 2018. 10(5). **Pneumococcal infection** The NICE surveillance review acknowledges a higher risk of pneumococcal infection for hospitalised people with coeliac disease. Research investigating the risk of community-acquired pneumonia among people with coeliac disease found that overall, people with coeliac disease had no increased risk of community-acquired pneumonia compared to controls, however among unvaccinated individuals, those with coeliac disease had a 28% increased relative risk of pneumonia (Zingone et al, 2016). The review also states that vaccination guidance is outside of the scope of the NICE guideline NG20 and therefore no impact on the guideline is expected. Producing vaccination guidance may be outside of scope for the NICE guidelines, however signposting to guidance from the Joint Committee on Vaccination and Immunisation, and highlighting that recommendations for people with coeliac disease are different to the general population due to an increased prevalence of hyposplenism is warranted to increase awareness among healthcare professionals and patients. Increased awareness and uptake of vaccination is required as only 26.6% of people were vaccinated after their diagnosis of coeliac disease (Zingone et al 2016). Zingone F, Abdul Sultan A, Crooks CJ, Tata LJ, Ciacci C, West J. The risk of community-acquired pneumonia among 9803 patients with coeliac disease compared to the general	coeliac disease. In developing NICE guideline NG20 the committee were unable to include the clinical features of DH in the list of criteria on when to offer serological testing (recommendation 1.1.1). We note that this resulted in a change in the recommendations around testing since the original NICE guideline CG86 was published in 2009. This change is in line with a change in NICE's methods of developing guidance, see the latest guideline development manual for more information about our processes. No additional eligible evidence was identified in the current 2019 surveillance review to indicate a potential impact on the recommendations in this area. Further evidence will be considered at the next surveillance review. **Pneumococcal infection** Thank you for the points raised concerning pneumococcal vaccination and risk of pneumonia. At the start of the guideline development process NICE held a consultation on the draft scope and a workshop for stakeholder organisations to provide direct feedback. The developers explained that participants at the stakeholder workshop felt that immunisation was not an area of significant controversy and did not need to be specifically mentioned. The consultation comments for the draft guidance showed that that pneumococcal vaccination wasn't mentioned by any of the stakeholders who commented on the draft guidance. As you acknowledged, new evidence identified in the 2019 surveillance review indicates a higher risk of pneumococcal infection for hospitalised people with CD. We note the study by Zingone et al. which will be added to the evidence summary and our conclusion to consider preventive pneumococcal vaccination will apply to

		population: a cohort study. Alimentary Pharmacology & Therapeutics 2016;44:57–67. doi:10.1111/apt.13652.	community-acquired as well as hospital-acquired pneumonia, in addition to those with functional hyposplenism. However, vaccination guidance is set at a national level by the UK government through the Joint Committee on Vaccination and Immunisation and is not within the scope of NICE guideline NG20. Therefore, no impact on the guideline is anticipated. A cross referral will be added to the guideline to the JCVI guidance on pneumococcal vaccination.
Royal College of Physicians	Yes	The RCP endorse the response submitted by the BSG.	Thank you for your comment. Please refer to the responses to the BSG comments for information.
Diabetes UK	Yes	While the surveillance review accepts that there is some new evidence surrounding serological testing for people with type 1 diabetes it is suggested that this new evidence does not warrant an update to the guidance. However, we would argue that **the guidelines should offer guidance on the frequency of testing**, which is currently does not, in light of the evidence reviewed. We also recommend that the **current wording in section 1.1.1** of the guideline "*offer serological testing…*" **should be strengthened to reflect the importance of routine testing** for those living with type 1 diabetes, rather than just for those showing symptoms. According to Coeliac UK only 30% of those who have coeliac disease have been diagnosed. Between 4% and 9% of people living with type 1 diabetes also have a diagnosis of coeliac disease which highlights the importance of	Thank you for your comments. **Type 1 diabetes** NICE guideline NG20 recommends (1.1.1) offering serological testing for CD to people with type 1 diabetes, at diagnosis. This is stronger wording than the 'consider' wording used in recommendation 1.1.2 and reflects the need for testing in this subgroup. It further recommends (1.1.6) advising 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. Recommendation 1.3.4 further advises that healthcare professionals should have a low threshold for re-testing people identified in recommendation 1.1.1, including those with type 1 diabetes, if they develop any symptoms consistent with coeliac disease.

		testing for it in this group - not least because for many people coeliac disease can be asymptomatic. **Section 1.6.4 refers to CG91** on depression in adults with a chronic physical health condition. We feel it is important to note that this guideline has not been updated since 2009 and does not make reference to people living with multiple chronic physical health conditions, for example, those living with coeliac disease and type 1 diabetes. **Managing two lifelong conditions concurrently has been shown to affect quality of life more markedly than managing one condition alone. We recommend that NG20 is updated to reflect this fact**. Read, J *et al.* (2017) 'Multimorbidity and depression: A systematic review and meta analysis', Journal of Affective Disorders, vol. 221, pp. 36-46. doi.org/10.1016/j.jad.2017.06.009	Since this advice allows for subsequent testing of people with type 1 diabetes, no impact on the guideline is anticipated. **Multimorbidity and depression** Thank you for indicating the need to update NICE guideline CG91 to take account of multimorbidity. This will be recorded in the issue log for that guideline for consideration at the next surveillance review. NICE also has a guideline on multimorbidity which health professionals are expected to follow in making decisions about people with CD.
Coeliac UK	Yes	**Dermatitis herpetiformis** Dermatitis herpetiformis (DH) should be considered within the scope of NG20 as it is the cutaneous manifestation of coeliac disease. Page 4 of the consultation document states that "the guideline committee did not find any evidence (based on criteria outlined in the search protocols) to indicate that testing for the existence of DH would be a reliable indicator of CD". People with DH often do not present with overt gastrointestinal symptoms (Reunala et al, 2018). Therefore,	Thank you for your comments. **Dermatitis herpetiformis** Thank you for your suggestions for including DH in the guideline recommendations. The research methods and discussion that led to these recommendations are in section 4.1.2 of the full guideline. In terms of the searches, the guideline committee suggested an exhaustive list of clinical signs and symptoms including co-existing conditions,

		based on the current list of symptoms within NG20 their diagnosis would be missed. Currently the only mention of DH within NG20 is under the "context" heading as an example of a non-gastrointestinal symptom. The clinical features of DH (including appearance and common sites for DH rash) should be included under the symptoms of coeliac disease rather than a diagnosis of DH as those already diagnosed with DH will have initiated a gluten free diet. Reunala, T., et al., Dermatitis Herpetiformis: A Common Extraintestinal Manifestation of Coeliac Disease. Nutrients, 2018. 10(5). **Pneumococcal infection** The NICE surveillance review acknowledges a higher risk of pneumococcal infection for hospitalised people with coeliac disease. Research investigating the risk of community-acquired pneumonia among people with coeliac disease found that overall, people with coeliac disease had no increased risk of community-acquired pneumonia compared to controls, however among unvaccinated individuals, those with coeliac disease had a 28% increased relative risk of pneumonia (Zingone et al. 2016). The review also states that vaccination guidance is outside of the scope of the NICE guideline NG20 and therefore no impact on the guideline is expected. Producing vaccination guidance may be outside of scope for the NICE guideline, however signposting to guidance from the Joint Committee on Vaccination and Immunisation, and highlighting that recommendations for people with coeliac disease are different to the general	prior to conducting the literature searches for this review question. This list included dermatitis herpetiformis, as you can see in the full list of search protocols (Appendix C). Studies were found linking dermatitis herpetiformis and coeliac disease but these were excluded in accordance with the predefined search protocols (see Appendix F for the full list of excluded studies and reasons for each exclusion). In summary, the review team did not find any evidence meeting the search protocols to indicate that testing for the existence of dermatitis herpetiformis would be a reliable indicator of coeliac disease. In developing NICE guideline NG20 the committee were unable to include the clinical features of DH in the list of criteria on when to offer serological testing (recommendation 1.1.1). We note that this resulted in a change in the recommendations around testing since the original NICE guideline CG86 was published in 2009. This change is in line with a change in NICE's methods of developing guidance, see the latest guideline development manual for more information about our processes. No additional eligible evidence was identified in the current 2019 surveillance review to indicate a potential impact on the recommendations in this area. **Pneumococcal infection** Thank you for the points raised concerning pneumococcal vaccination and risk of pneumonia. At the start of the guideline development process NICE held a consultation on the draft scope and a workshop for stakeholder organisations to provide direct feedback. The developers explained that participants at the stakeholder workshop felt that immunisation was not an area of significant controversy and did not need to be specifically mentioned. The consultation comments for the draft guidance showed that that pneumococcal vaccination wasn't

		population due to an increased prevalence of hyposplenism is warranted to increase awareness among healthcare professionals and patients. Increased awareness and uptake of vaccination is required as only 26.6% of people were vaccinated after their diagnosis of coeliac disease (Zingone et al. 2016). Zingone F, Abdul Sultan A, Crooks CJ, Tata LJ, Ciacci C, West J. The risk of community-acquired pneumonia among 9803 patients with coeliac disease compared to the general population: a cohort study. Alimentary Pharmacology & Therapeutics 2016;44:57–67. doi:10.1111/apt.13652.	mentioned by any of the stakeholders who commented on the draft guidance. As you have alluded to, new evidence identified in the 2019 surveillance review indicates a higher risk of pneumococcal infection for hospitalised people with CD. We note the study by Zingone et al. which will be added to the evidence summary and our conclusion to consider preventive pneumococcal vaccination will apply to community-acquired as well as hospital-acquired pneumonia, in addition to those with functional hyposplenism. However, vaccination guidance is set at a national level by the UK government through the Joint Committee on Vaccination and Immunisation and is not within the scope of NICE guideline NG20. Therefore, no impact on the guideline is anticipated. A cross referral will be added to the guideline to the JCVI guidance on pneumococcal vaccination.
Fountain practice, Bourne Hall Health centre	No	Not answered	Thank you.
British Dietetic Association	No	Not answered	Thank you.
Royal College of Paediatrics and Child Health	No	Not answered	Thank you.
Royal Osteoporosis Society	Not Answered	No	Thank you.

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BSPGHAN. British Society of Paediatric Gastroenterology Hepatology and Nutrition	Yes	A.Management of the condition needs to be reviewed. I see that you have commented on pneumococcal infection and also folate in pregnancy. Two government bodies have concluded on these issues. It is clear to me that GPs and secondary care colleagues are still unaware of these changes in policy and need to be flagged up or at least referenced in an update of the NG20 guideline.	Thank you for your comments. **Folic acid supplementation** No evidence was identified to substantiate the Clinical Knowledge Summary (CKS) advice for high-dose folic acid supplementation (5 mg once daily) for women with CD who are pregnant, or who are planning a pregnancy. CKS must not differ from NICE guidance on matters where NICE guidance exists but can use its own methods to produce additional advice on other matters. CKS does not constitute formal NICE guidance, and until evidence indicates otherwise, no impact on the guideline is anticipated. The CKS advice will be amended to align with NICE guideline NG20. NICE's guideline on maternal and child nutrition provides further advice in this area. **Pneumococcal infection** At the start of the guideline development process NICE held a consultation on the draft scope and a workshop for stakeholder organisations to provide direct feedback. The developers explained that participants at the stakeholder workshop felt that immunisation was not an area of significant controversy and did not need to be specifically mentioned. The consultation comments for the draft guidance showed that that pneumococcal vaccination wasn't mentioned by any of the stakeholders who commented on the draft guidance. New evidence identified in the 2019 surveillance review indicates a higher risk of pneumococcal infection for hospitalised people with CD. Preventive pneumococcal vaccination should be considered for this subgroup, in addition to those with functional hyposplenism. However, vaccination guidance is set at a national level by the UK

			government through the Joint Committee on Vaccination and Immunisation and is not within the scope of NICE guideline NG20. Therefore, no impact on the guideline is anticipated. A cross referral will be added to the guideline to the JCVI guidance on pneumococcal vaccination.
3. Do you have any comments on equalities issues?			
Stakeholder	**Overall response**	**Comments**	**NICE response**
Quality & Leadership Team – NICE	No	Not answered	Thank you.
Sandwell and West Birmingham NHS Trust	No	Not answered	Thank you.
British Society of Gastroenterology (BSG)	Yes	**Gluten free prescribing** Since the NICE guideline NG20 was published in 2015, there have been significant changes to access to gluten free food on prescription in England. In England, gluten free prescribing policies are decided by clinical commissioning groups (CCGs) which has led to unequal access to gluten free food on prescription. This prompted a national consultation on the future of gluten free prescribing which was launched in 2017 by the Department of Health. In 2018, the decision was announced to retain access to gluten free bread and flour mixes on prescription and to blacklist other foods such as breakfast cereals and pasta. NHS England has subsequently published guidance for CCGs with reference to the need to reduce the variation in gluten free prescribing across England. However, the guidance also states clearly that CCGs as policymakers have the right to completely remove access to gluten free	Thank you for your comments. **Prescription of gluten free foods** The guideline does not make recommendations on prescribing of gluten free foods because policy and legislation in this area is set at a national level by the Department for Health and Social Care, with implementation passed to CCGs at a local and regional level. No impact is anticipated on the guideline.

		food on prescription. Gluten free prescribing therefore presents a source of inequality for people with coeliac disease in England with access to key staples on prescription determined by postcode rather than clinical need. Access to gluten free food on prescription is important for people with coeliac disease to support their diet due to the high cost and limited availability of gluten free staple foods. There are several published papers documenting the fact that gluten free foods are 3-4 times more expensive than gluten containing equivalents and are not available in convenience stores and budget supermarkets (Hanci et al, 2019, Burden et al 2015, Singh et al 2011). These factors present an equality issue for people with coeliac disease on low incomes or with limited mobility. In addition, coeliac disease can affect more than one member of the family which can lead to significant increase in food costs. Across Wales, Northern Ireland and Scotland, people with coeliac disease can access a range of gluten free staple foods on prescription. In Scotland, access to gluten free foods is via the Gluten Free Food Service, a pharmacy led service providing access to gluten free staple foods and an annual health check through community pharmacy. In Wales, Hywel Dda Health Board is running a pilot scheme with a pre-loaded chip-and-pin card (which aims to provide the difference in cost between gluten free and gluten containing staple foods). Hanci, O. and Y.M. Jeanes, Are gluten free food staples accessible to all patients with coeliac disease? Frontline Gastroenterol, 2019. 10(3): p. 222-228. Singh, J. & Whelan, K. (2011). Limited availability and higher cost of gluten free foods. Journal of Human Nutrition and Dietetics, 24, 479-486.	

		Burden, M., et al., (2015) Cost and availability of gluten free food in the UK: in store and online. Postgraduate Medical Journal, 2015: p. postgradmedj-2015-133395	
Royal College of Physicians	Yes	The RCP endorse the response submitted by the BSG.	Thank you for your comment. Please see the response to the BSG comments for further information.
Diabetes UK	Not answered	Not answered	Thank you.
Coeliac UK	Yes	**Gluten free prescribing** Since the NICE guideline NG20 was published in 2015, there have been significant changes to access to gluten free food on prescription in England. In England, gluten free prescribing policies are decided by clinical commissioning groups (CCGs) which has led to unequal access to gluten free food on prescription. This prompted a national consultation on the future of gluten free prescribing which was launched in 2017 by the Department of Health. In 2018, the decision was announced to retain access to gluten free bread and flour mixes on prescription and to blacklist other foods such as breakfast cereals and pasta. NHS England has subsequently published guidance for CCGs with reference to the need to reduce the variation in gluten free prescribing across England. However, the guidance also states clearly that CCGs as policymakers have the right to completely remove access to gluten free food on prescription. Gluten free prescribing therefore presents a source of inequality for people with coeliac disease in England with access to key staples on prescription determined by postcode rather than clinical need. Access to gluten free food on prescription is important for people with coeliac disease to support their diet due to the high cost and limited availability of gluten free staple foods.	Thank you for your comments. **Prescription of gluten free foods** The guideline does not make recommendations on prescribing of gluten free foods because policy and legislation in this area is set at a national level by the Department for Health and Social Care, with implementation passed to CCGs at a local and regional level. No impact is anticipated on the guideline.

		There are several published papers documenting the fact that gluten free staple foods are 3-4 times more expensive than gluten containing equivalents and are not available in convenience stores and budget supermarkets (Hanci et al. 2019, Burden et al. 2015, Singh et al. 2011). These factors present an equality issue for people with coeliac disease on low incomes or with limited mobility. In addition, coeliac disease can affect more than one member of the family which can lead to significant increase in food costs. Across Wales, Northern Ireland and Scotland, people with coeliac disease can access a range of gluten free staple foods on prescription. In Scotland, access to gluten free foods is via the Gluten Free Food Service, a pharmacy led service providing access to gluten free staple foods and an annual health check through community pharmacy. In Wales, Hywel Dda Health Board is running a pilot scheme with a pre-loaded chip-and-pin card (which aims to provide the difference in cost between gluten free and gluten containing staple foods). Hanci, O. and Y.M. Jeanes, Are gluten free food staples accessible to all patients with coeliac disease? Frontline Gastroenterol, 2019. 10(3): p. 222-228. Singh, J. & Whelan, K. (2011). Limited availability and higher cost of gluten free foods. Journal of Human Nutrition and Dietetics, 24, 479-486. Burden, M., et al., (2015) Cost and availability of gluten free food in the UK: in store and online. Postgraduate Medical Journal, 2015: p. postgradmedj-2015-133395	
Fountain practice, Bourne Hall Health centre	No	Not answered	Thank you.

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British Dietetic Association	Yes	The consultation included an impact assessment, with particular relevance to the legal duties of CCGs to advance equality and have regard to reducing health inequalities. We strongly suggestion the inclusion of recommending prescription of gluten free foods for patients with coeliac disease as outlined for England (GF breads and flour mixes only), Wales, Scotland and Northern Ireland. "*Families who are on low incomes or families on no-incomes pending benefit decision outcomes, are likely to feel a greater impact from any changes as 80% of GF, GF/WF prescription items are exempt from prescription charges..*"[3] *"Patients living in rural areas [and those without car ownership] who have limited transport options may also find it difficult to source formulated GF food locally as it is may not frequently be stocked by smaller/local retailers."*[3] A recent study (2019) highlights the high cost and minimal availability of gluten free formulated foods in budget stores persists[2].	Thank you for your comments. **Prescription of gluten free foods** The guideline does not make recommendations on prescribing of gluten free foods because policy and legislation in this area is set at a national level by the Department for Health and Social Care, with implementation passed to CCGs at a local and regional level. No impact is anticipated on the guideline.
Royal College of Paediatrics and Child Health	No	Not answered	Thank you.
Royal Osteoporosis Society	Not answered	In Coeliac guidance 1.4.4. (Need for DXA), reference is made to request for DXA being based on CG146, which is for adults only. There is no mention of what should be	Thank you for your comments. **Bone health assessment in children**

		done for bone health assessment for children (under 18 yrs) CG146 is quite robust for those aged under 40 yrs in promoting the need for a DXA in those "who have a major risk factor, such as history of multiple fragility fracture, major osteoporotic fracture, or current or recent use of high-dose oral or high-dose systemic glucocorticoids". There is no mention of "secondary osteoporosis" and by implication no DXA required for patients with coeliac disease.	The surveillance review did not identify any evidence on bone health assessment for children under 18 years. New evidence will be assessed at the next surveillance review. **NICE guideline CG146** Thank you for highlighting the need to mention secondary osteoporosis in NICE guideline CG146. We will record your comment in the issue log for the consideration at the next surveillance review of this guideline.
BSPGHAN. British Society of Paediatric Gastroenterology Hepatology and Nutrition	Yes	A.I do not agree with your conclusion page 4 – you saw no equality issues during the process. You must be assuming that the DOH addressing prescriptions after the consultation has addressed the inequalities flagged up in the impact assessment (detailed below). Since the DOH consultation of GF food availability on prescription which decided to continue prescriptions in England, there is clear evidence that many CCGs have still unilaterally taken away all prescription items and continue to do so despite the decision to retain GF prescription items, however limited. If there continues to be a postcode lottery of prescribing from CCGs, then the inequalities remain. This is still a postcode lottery and surely must bring inequality into the issue. It is expensive to live gluten free and children are amongst the most socioeconomically vulnerable, especially when they come from families who have multiple members	Thank you for your comments. **Prescription of gluten free foods** The guideline does not make recommendations on prescribing of gluten free foods because policy and legislation in this area is set at a national level by the Department for Health and Social Care, with implementation passed to CCGs at a local and regional level. No impact is anticipated on the guideline.

		who need to live GF. This is true inequality. Government policy is being ignored in many areas. This should be addressed by a review of the current guidelines B. link to the consultation https://www.gov.uk/government/consultations/gluten-free-foods-on-nhs-prescription C. link to the equality impact assessment Socio-economic issues are dealt with in paragraphs 3.43 to 3.53. . see also table 1 and point 1.4 See also summary of impacts 3.56. this concludes that there are inequalities. They clearly still exist IF CCGs still unilaterally decide not to prescribe GF items https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/678183/Equality_impact_assessment_-_GF_food.pdf	