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Nationwide survey of coeliac disease serology testing in the UK

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ABSTRACT

Objective Recent evidence supports diagnosing coeliac disease without biopsy in patients with significantly elevated tissue transglutaminase (IgA-tTG) antibodies. However, the implementation of this no-biopsy approach relies on accurate and consistent serological testing across laboratories. In this nationwide survey, we aimed to evaluate the availability and variability of coeliac disease testing across the UK.

Methods We conducted a cross-sectional telephone survey of biomedical scientists and laboratory managers from National Health Service trusts and health boards across England, Wales, Scotland, and Northern Ireland. Data collected included assay types, reporting methods, upper limit of normal (ULN) thresholds, turnaround times, total IgA testing, and anti-endomysial antibodies (EMAs) availability.

Results A total of 356 sites were approached, with a 96% response rate (n=342). Of responding sites, 177 performed coeliac serology tests in-house, while 165 transferred samples externally. Among sites performing tests, 12 different IgA-tTG assays were identified, with considerable variability in ULN thresholds ranging from 3 to 30 IU/mL, even within laboratories using the same assays. The median turnaround time for IgA-tTG results was 7 days (range 1–21 days). Only 43% of laboratories routinely measured total IgA when IgA-tTG was requested. EMA testing was available in 83% of laboratories.

Conclusion Significant variability exists in coeliac serology testing across UK laboratories which poses a challenge for the implementation of the no-biopsy approach in clinical practice. Efforts to standardise serological testing are urgently needed. Until such standardisation is achieved, local assay validation remains critical.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The no-biopsy approach to diagnose coeliac disease is increasingly adopted in selected patients with significantly elevated tissue transglutaminase (IgA-tTG) antibodies. However, its reliability depends on consistent, high-quality serological testing.
⇒ There are concerns about variations in coeliac serology assay performance and laboratory testing practices.

WHAT THIS STUDY ADDS

⇒ We found significant variations in IgA-tTG assays, positivity thresholds, total IgA measurements, and endomysial antibody testing availability across different laboratories.
⇒ The upper limit of normal for IgA-tTG varied significantly even among laboratories using the same assay from the same manufacturer.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The findings of this nationwide survey highlight the need for national standardisation of coeliac disease serology testing to ensure the safe implementation of the no-biopsy approach in clinical practice.

INTRODUCTION

Coeliac disease is a chronic immune-mediated disorder triggered by the ingestion of gluten in genetically predisposed individuals.[1] Despite the substantial rise in the incidence of coeliac disease in the UK over the past two decades, it is estimated that most patients remain undiagnosed, misdiagnosed or experience significant delays before receiving a formal diagnosis.[2 3] These diagnostic delays contribute to ongoing morbidity and associated complications such as nutritional deficiencies, anaemia, and increased risk of malignancy.[4 5]

For decades, the diagnosis of coeliac disease relied on histological confirmation of villous atrophy on duodenal biopsies. However, recent evidence suggests that in patients with very high levels of coeliac-specific antibodies (IgA tissue transglutaminase (tTG) ≥10× the upper limit of normal (ULN)), a no-biopsy diagnosis is not only highly accurate but also preferred by both patients and clinicians.[6–9] This no-biopsy approach avoids the need for invasive endoscopy, reduces associated risks, and leads to significant cost savings.[10] Yet, its successful implementation relies on the accuracy of serological testing, which can be compromised by variations in

assay performance and discrepancies in reported ULN between laboratories.[11 12]

In this nationwide survey, we aimed to provide essential data on the availability and variability of coeliac disease serological testing across the UK to ensure that the no-biopsy approach is safe and feasible for widespread clinical adoption.

METHODS

Study design

We conducted a nationwide cross-sectional study using a telephone survey of biomedical scientists and laboratory managers working in National Health Service (NHS) hospital trusts and health boards that offer coeliac disease serology testing in England, Wales, Scotland and Northern Ireland. The study was reported according to the CROSS (Consensus-based checklist for Reporting of Survey Studies),[13] provided in the online supplemental material.

Patient and public involvement

The study was directly informed by two patient and public involvement and engagement groups in Sheffield and Bristol. These groups contributed to the development of the study aims and survey design by highlighting the impact of delayed and inconsistent coeliac disease diagnosis on patient experience. Patients emphasised the importance of understanding national testing variability to improve diagnostic accuracy and accessibility.

Setting and participants

We identified potentially eligible laboratories by collating a list of all NHS hospital trusts and health boards in the UK from the NHS digital database and the nidirect government services website.[14 15] Laboratories were eligible to participate if they offered coeliac serology testing (ie, offered IgA-tTG and/or anti-endomysial antibody (EMA) testing). We excluded private laboratories and those located outside the UK.

Recruitment and consent

We obtained the contact details of each laboratory within the identified NHS trusts and health boards. A member of our research team then telephoned potential participants, explained the purpose and scope of the study, and invited them to participate. Oral consent was requested and documented before proceeding with the survey. Individuals were informed that participation was voluntary and that they could withdraw at any time without providing a reason or facing any repercussions.

Data collection

A structured questionnaire was developed and piloted to capture consistent information across sites. The questionnaire sought data on the availability of IgA-tTG and EMA tests, assay types, reporting methods (quantitative or qualitative outputs), cut-off thresholds (eg, ULN for IgA-tTG titres), automatic reporting of total IgA levels, turnaround times, costs, and the communication of test interpretations.

All survey interviews were conducted via telephone. In circumstances where initial contact was incomplete or the participant requested more time, follow-up calls were scheduled to obtain missing information. Responses were logged in real-time on a secure, standardised spreadsheet. After each survey, we reviewed responses for completeness and clarity to minimise missing data and potential reporting bias. Where specific data points remained unavailable following phone calls, we completed those items using publicly accessible information from laboratory websites.

Statistical analysis

We used descriptive statistics to outline patterns in test availability and variability of diagnostic thresholds. Frequencies and percentages were calculated for categorical variables, while continuous variables were summarised using medians and IQRs. All statistical analyses were performed using Stata V.18 (StataCorp, College Station, Texas, USA).

RESULTS

Participation and response rate

The survey was conducted between the 25 January and 14 March 2025. In total, 188 NHS trusts and health boards, encompassing 356 individual sites, across the UK were approached to participate. Of these, 342 (96%) provided survey responses, while the remaining 14 (4%) did not respond or declined to participate. Among the 342 responding sites, 165 indicated that they transferred their coeliac serology samples to a different site for processing, and 177 conducted the testing in-house. Of those 177 in-house testing sites, 131 (74%) provided complete responses, and 46 (26%) offered partial data (figure 1).

Availability of coeliac disease serology testing

All responding sites (n=177) offered IgA-tTG testing, and 130/156 (83.3%) offered EMA testing. Total IgA testing was available in 150/154 (97.4%) sites. However, only 66 (43%) offered reflex total IgA testing when IgA-tTG is requested.

Serological assays and IgA-tTG upper limit of normal

In total, 12 unique IgA-tTG assays from various manufacturers were identified across participating laboratories. The most commonly used assays were Thermo Fisher EliA Celikey (n=104 sites, 65.8%), ORGENTEC (n=14 sites, 9%), Werfen BIO-FLASH (n=12 sites, 7.6%), Bio-Rad BioPlex (n=9 sites, 5.7%), and Aptiva Celiac Disease IgA Reagents (n=7 sites, 4.4%), with the remaining assays each used across five sites or less (figure 2). Only one site reported offering qualitative (positive or negative) rather than quantitative IgA-tTG results. There was a significant variation in the IgA-tTG ULN across laboratories, ranging between 3 and 30 IU/mL (figure 3). This

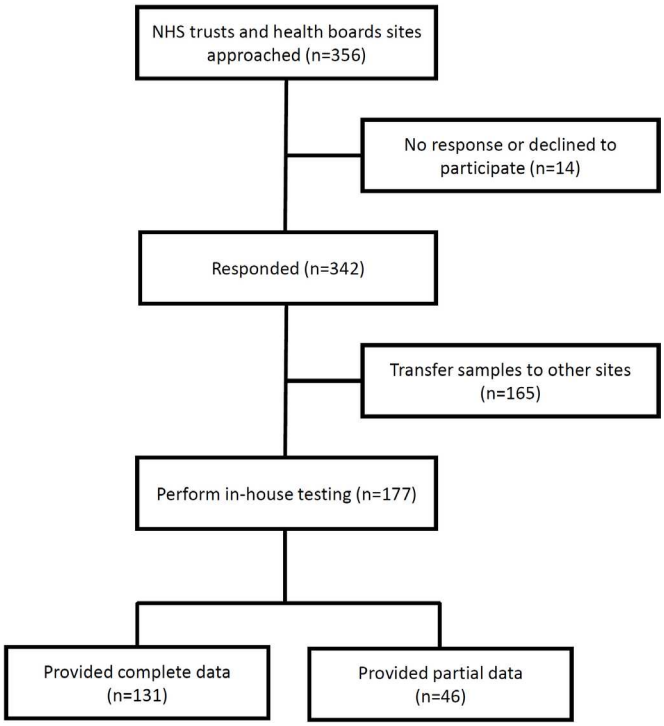

Figure 1 Study flowchart. NHS, National Health Service.

variation existed even among laboratories using the same manufacturer's assays (online supplemental table 1).

Turnaround times, reporting and cost

Participants reported varying turnaround times, ranging from 24 hours to 3 weeks. The median turnaround time for IgA-tTG testing was 7 days (IQR 3–7 days). As shown in figure 4 the most frequently reported turnaround time was 7 days (n=55 sites, 33%), followed by 3 days (n=25, 15%), 5 days (n=24, 14%), and 14 days (n=15, 9%). In terms of result reporting, 105 out of 149 sites (70.4%) provided interpretative advice or clinical guidance alongside the test results. None of the respondents disclosed specific test costs.

Regional variation in coeliac disease serology testing

We observed substantial variation in testing practices between UK regions as summarised in table 1. The

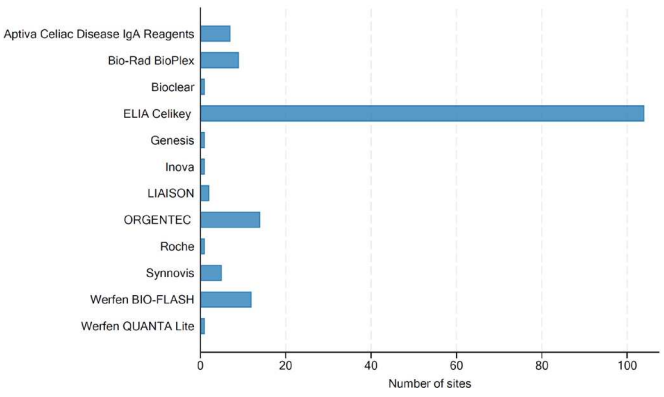

Figure 2 The number of sites using each commercial assay for tissue transglutaminase (tTG) testing.

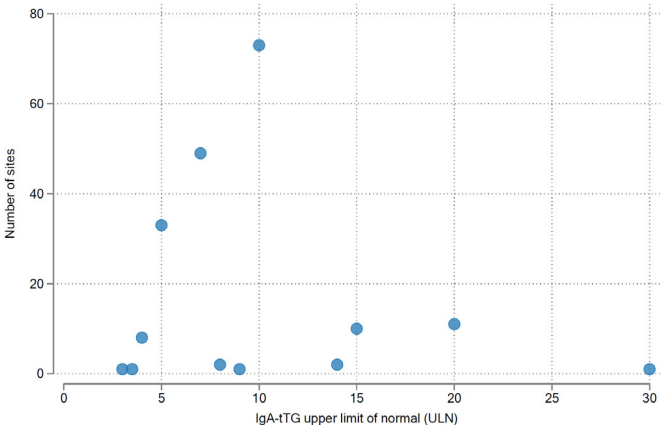

Figure 3 Variations in the upper limit of normal of IgA-tTG across different sites. IgA-tTG, IgA tissue transglutaminase.

number of different IgA-tTG assays used by region ranged from 1 to 5, with ULN values ranging from 3 to 30 IU/mL. Only Northern Ireland reported using a single assay with a fixed ULN across all sites. Turnaround times varied widely with results being reported within a week in some regions and up to 3 weeks in other regions. The proportion of sites routinely measuring total IgA ranged from none in Scotland to over 70% in the North East and South West. EMA availability was lowest in the South East of England, and highest in the South West, Wales and Northern Ireland.

DISCUSSION

In this nationwide survey, we found wide variations in coeliac serology testing practices across the UK. There was considerable heterogeneity in the types of serological assays used for tTG and the ULN values reported, with thresholds ranging widely between 3 and 30 IU/mL. Even among laboratories using the same assay from the same manufacturer, reported ULN values differed significantly. EMA testing was available in approximately 80% of laboratories, and only 43% measured total IgA routinely when IgA-tTG was requested.

A 2015 survey of NHS trusts providing paediatric coeliac disease testing in England identified four different tTG

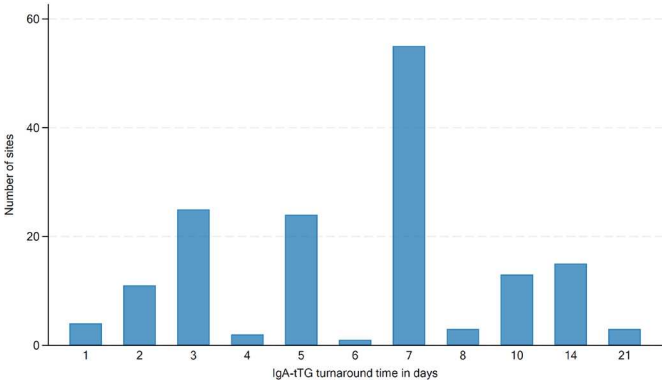

Figure 4 Variations in turnaround time of IgA-tTG across different sites. IgA-tTG, IgA tissue transglutaminase.

Table 1 Regional variation in coeliac disease serology testing across the UK

Country	Region	Sites (n)	IgA-tTG assays (n)	IgA-tTG ULN range (IU/mL)	IgA-tTG turnaround time (range in days)	Total IgA routinely measured (%)	EMA availability (%)
England	North East	14	4	7–20	1–21	77	84.6
	North West	12	2	7–10	1–14	33.3	70
	Yorkshire and the Humber	8	4	7–20	5–14	42.8	87.5
	Midlands	27	4	4–30	1–10	66.6	80
	East of England	13	2	3.5–10	2–14	45.4	81.8
	London	28	4	5–15	1–21	56	96
	South East	11	5	7–20	2–8	33.3	63.6
	South West	10	2	3–15	3–14	71.4	100
Wales		9	3	4–20	3–10	62.5	100
Scotland		38	4	4–15	3–14	0	76.3
Northern Ireland		7	1	5	7–10	66.6	100
Total		177	12	3–30	1–21	43	83

EMA, endomysial antibody; IgA-tTG, IgA tissue transglutaminase; ULN, upper limit of normal.

assays in use, highlighting variability in ULN among laboratories and assays.[16] Our study shows that this variability has significantly increased, with 12 different tTG assays now used across UK laboratories. This variation in assays and ULN thresholds has important implications for implementing the no-biopsy approach in clinical practice. The no-biopsy approach relies on consistent and reliable IgA-tTG measurements. However, with different assays producing varying ULN thresholds, the actual antibody level corresponding to the diagnostic cut-off of ≥10×ULN can differ significantly between laboratories. For example, a patient with an IgA-tTG level of 100 IU/mL meets the no-biopsy diagnosis criteria in a laboratory using an assay with an ULN of 7 IU/mL, but not in a laboratory using an assay with a ULN of 15 IU/mL. This inconsistency may lead to misdiagnosis, where some patients are incorrectly diagnosed with coeliac disease, or to inappropriate use of biopsies, either unnecessarily performed or avoided when needed. Moreover, our data shows that both enzyme and chemiluminescent immunoassays are in use in routine clinical practice to measure IgA-tTG titres; there is less data available on the accuracy of the latter for the no-biopsy diagnosis in adult coeliac disease.[17]

One of the key criteria set by the UK National Screening Committee is the existence of an agreed threshold for test positivity. Without standardisation, inconsistencies in test interpretation could undermine the effectiveness, equity, and cost-efficiency of a screening programme.[18] Our findings highlight this challenge and have important implications for any potential screening programme for coeliac disease in the UK.

Both the European Society Paediatric Gastroenterology, Hepatology and Nutrition Guidelines and the British Society of Gastroenterology interim guidance include confirmatory EMA testing as part of the no-biopsy approach to diagnose coeliac disease.[19 20] Currently, there is no universally agreed-upon minimal threshold for EMA positivity, and laboratories often report results qualitatively, which is subject to variability. Our findings show that EMA testing is available in approximately 80% of sites across the UK. However, it is subjective, labour-intensive, and more expensive than tTG testing.[21] In a recent meta-analysis including 12 103 participants from 15 countries, a single measurement of IgA-tTG≥10×ULN had a specificity of 100% and a positive predictive value (PPV) of 98% to identify coeliac disease in patients with a high pretest probability.[7] This excellent PPV suggests that relying solely on a single IgA-tTG measurement is sufficient to make an accurate diagnosis of coeliac disease without the need for biopsies or confirmatory EMA testing. The high performance of IgA-tTG titres ≥10×ULN remained consistent across various commercial assays with different positivity thresholds.[7]

Despite recommendations in clinical guidelines to measure total IgA levels alongside coeliac serology,[19 22 23] we found that most laboratories across the UK do not routinely measure total IgA when IgA-tTG is requested. This is concerning as the prevalence of selective IgA deficiency in patients with coeliac disease is 10–16 times higher than in the general population.[24] Without measuring total IgA, patients with IgA deficiency may receive false-negative results, leading to delayed and missed diagnoses. Moreover, patients with IgA deficiency or seronegative coeliac disease may have a more aggressive disease phenotype and higher risks of complications and mortality compared with those with seropositive coeliac disease.[25] Therefore, failure to routinely measure total IgA may have significant implications for patient outcomes.

Our study has several strengths. First, we achieved a very high response rate from laboratories in England, Wales, Scotland and Northern Ireland. This ensured that our findings accurately reflect current practices across the UK. Second, we captured detailed information on assay types, ULN thresholds, and turnaround times which allowed us to identify areas of variation. Third, our study provides a robust foundation for policy development by identifying critical barriers to the implementation of the no-biopsy approach, particularly the variability in assays and ULN thresholds. These findings highlight the urgent need for collaboration among clinicians, stakeholders, and industry partners to standardise assays and harmonise reference ranges across laboratories. Until such standardisation is achieved, local validation of assays and careful interpretation of serology results remain essential to ensure accurate and reliable diagnosis.

This study also had limitations. As a cross-sectional survey, the data relied on self-reported information from laboratory personnel, which may be subject to reporting inaccuracies. Although we sought to minimise this by verifying incomplete responses using publicly available sources, some inaccuracies may persist. Furthermore, we did not assess the diagnostic accuracy of the different assays used across the UK or the clinical implications of the reported variations in serological testing practices. While we did not specifically assess the upper limit of detection for each assay, most quantitative assays in clinical use report values high enough to determine whether the 10× ULN threshold has been reached. Finally, we were unable to provide detailed cost comparisons between laboratories, as none of the respondents disclosed specific test costs.

In conclusion, our study demonstrates substantial variability in coeliac serology assays and ULN thresholds across UK laboratories. This heterogeneity poses a challenge for the implementation of the no-biopsy approach in clinical practice. Efforts to standardise serological testing through multidisciplinary collaboration are essential to ensure consistent and accurate diagnosis of coeliac disease.

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Contributors Conception: ME, PW, MGS, HAP. Data collection: AA, ASH, MD, MIZ, MA. Statistical analysis and data visualisation: MGS. Initial drafting of the manuscript: AA, MGS. Protocol revisions, data interpretation, critical revision of the manuscript and final approval of the submitted version: AA, ASH, MD, MIZ, MA, GW, HAP, DSS, PW, ME, MGS, JW, CEF, DL, HU, KS, KC, HEJ, SM, GR, YX, IL-W, PG, RB, HT. MGS is the guarantor.

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Competing interests MGS and HAP received speaker fees from Thermo Fisher. The other authors declare no competing interests.

Patient consent for publication Not applicable.

Ethics approval According to the UK Health Research Authority decision tool, this work was classified as a service evaluation and therefore did not require formal ethical approval. A second opinion was sought from the University of Bristol's ethics department, which confirmed that no formal ethical approval was needed. Nonetheless, we adhered to the principles of Good Clinical Practice.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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