Development of a harmonised pathways for Coeliac Disease across Mid and South Essex

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One team working together for excellent patient care

Introduction

Mid and South Essex NHS Foundation Trust (MSEFT) is the sole hospital within the Mid and South Essex Integrated Care System (MSEICS) providing services for Southend, Basildon and Broomfield Hospitals. MSEICS aspires to meet the health requirements and reduce health inequalities for the 1.2 million population living within the MSE geography. Pathology services are provided by a private-NHS partnership with SYNLAB, Pathology First (PF), for Southend and Basildon with Broomfield offering an NHS-managed service. PF Immunology services are provided from a centralised hub laboratory with the Broomfield Immunology laboratory located at the Hospital. This split-model for laboratory services results in lack of equitability for patients, whilst limiting financial and operational efficiencies.

Laboratory pathways are often historical and due to complexities and integration within clinical pathways are difficult to transform and change. Current laboratory testing pathways for patients across MSEFT differ depending upon laboratory site and patient location.

Aim

To develop a single laboratory testing pathway for Coeliac Disease (CD) across MSEFT regardless of laboratory location. This would support equitability for patients across the ICS whilst offering financial and operational benefits from a single service model.

Methods

Multifactorial methodology was utilised for this study including: -

Qualitative analysis: - thematic analysis of a review of current CD best practice and guidelines supported by a review of local processes was performed

Stakeholder engagement: - Clinical and laboratory stakeholder forums identified key areas of concern and stakeholder requirements

Quantitative analysis: - review of current workload was performed to enable different testing pathways to be financially analysed based upon current and future costing templates to determine best value for money

The mixed methodology approach identified key discrepancies in service provision within MSEFT and supported the development of a cost-effective harmonised CD pathway, whilst meeting stakeholder requirements and guideline compliant

Results

1. Academic research thematic analysis

- tTG IgA is the best test for front line screening, supplemented with an IgG-based test (tTG IgG, EMA IgG, DPG IgG) in IgA-deficiency
- Second line confirmatory IgA-based test (EMA IgA, DGP IgA) to be used to confirm borderline tTG IgA cases
- The use of EMA IgA in the non-biopsy approach in paediatrics with tTG IgA >= 10XURN
- Minimum retesting intervals are proposed by the Royal College of Pathologists
- Passionate in providing equitability across MSEICS whilst complying with national guidelines and development of cost and efficiency benefits

2. Clinical stakeholder focus groups

- Clinicians are unclear on testing process and request additional tests due to lack of clarity in process
- Keen to adopt non-biopsy approach in paediatrics but lack guidance
- Passionate in providing equitability across MSEICS whilst complying with national guidelines and development of cost and efficiency benefits

3. Single pathway

- Using findings from the academic thematic analysis and stakeholder engagement a single diagnostic testing pathways is proposed
- <age range refers to results less than age related reference range figure 1, table 1)

Figure 1: Proposed single laboratory testing pathway

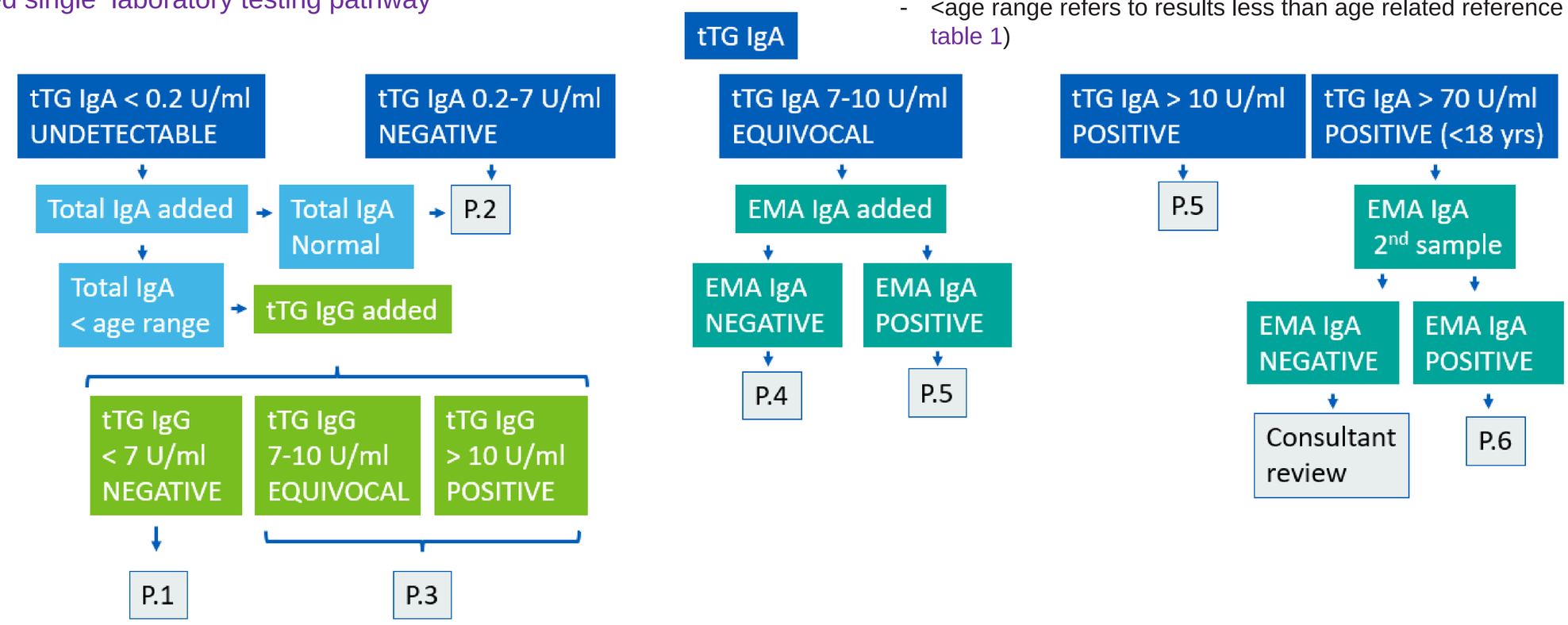

Table 1 :Proposed interpretative comments

P.1	Does not support a diagnosis of CD; however, if the clinical suspicion is very high suggest a small bowel biopsy
P.2	Anti-tTG IgA antibodies Negative: Does not support a diagnosis of CD, however, if the clinical suspicion is very high, suggest small bowel biopsy. Serology will become negative once the patient is on a gluten free diet and false negatives occur in complete IgA deficiency
P.3	In the presence of IgA deficiency; these results suggest that CD should be actively excluded. Suggest referral to gastroenterologist if clinical suspicion is high (laboratory note to send away for EMA IgG analysis if specifically requested
P.4	Anti-tTG IgA antibodies weakly positive. In accordance with NICE guidelines we have tested for IgA endomysial antibodies which are NEGATIVE. The results are not suggestive of CD, however, referral to a gastroenterology specialist for biopsy may still be indicated for definitive diagnosis (NICE guidance NG20, 2015)
P.5	Suggestive of active CD or poor adherence to gluten-free diet. If patient is not known to have CD referral for further gastroenterological investigation, including duodenal biopsy, is suggested as per current BSG and ESPGHAN guidelines for the management of suspected CD
P.6	Positive IgA endomysial antibodies consistent with CD. A no-biopsy approach is confirmed to be safe in children with tTG IgA >=70 U/ml and positive IgA endomysial antibodies in a second sample (ESPGHAN, 2020)

4. Financial analysis

To determine the cost effectiveness of the proposal, the pathway was retrospectively applied to a 6-month workload data set for each stie. Clinical review and application of predictive methodology estimated the predicted workload. Key findings included:-

- tTG IgA reduced by 2% through application of minimum retesting intervals (Royal College of Pathologists, 2021)
- IgA increased by 85% as testing when tTG IgA <0.2 U/ml (NICE, 2015; ESPGHAN, 2020)
- tTG IgG reduced by 78% as testing when IgA< age reference range (NICE, 2015; ESPGHAN, 2020)
- EMA IgA reduced by 71% as testing when <18yrs when tTG IgA>=10XULN (ESPGHAN, 2020)
- EMA IgG discontinued and offered as case-by-case referral test (NICE, 2015)

The predicted test cost for the CD proposal estimated annual cost saving £14, 420.

Additional financial and non-financial benefits for the MSEICS outside the testing pathway for patients, clinicians, operational laboratory processes and the MSCICS should be embraced

£14, 420 annual savings

Conclusions

- This single pathway is central to diagnostic stewardship offering equitability for patients across the ICS whilst offering financial and operational benefits from a single service model.
- This model may provide a flagship for future harmonisation pathways internally and externally.

References

- ESPGHAN, (2020). *New Guidelines for the Diagnosis of Paediatric Coeliac Disease*
- National Institute Clinical Excellence, (2015). *Coeliac disease: recognition, assessment and management*
- Royal College of Pathologists, (2021). *National minimum retesting intervals in pathology*.