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Quality Indicators for the Diagnosis and Management of Eosinophilic Esophagitis

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Abstract

INTRODUCTION: Despite best practice recommendations for managing eosinophilic esophagitis (EoE), variation in care exists.

METHODS: We used established methodology for quality indicator development to identify metrics to define quality for the treatment of EoE.

RESULTS: Among 29 proposed quality indicator statements, 9 (31%) were adopted as highly valid across all categories. Two (22%) of these statements were identified as having existing or suspected quality gaps.

DISCUSSION: We identified highly valid EoE quality indicators for adult gastroenterologists, which can be used for quality improvement with resulting benefits for patient outcomes.

Keywords

Eosinophilic esophagitis; Quality indicators; Practice quality; Quality improvement

INTRODUCTION

Eosinophilic esophagitis (EoE) is a chronic, allergic inflammatory condition with rising incidence and prevalence that can lead to esophageal dysfunction (1). Guidelines and consensus documents (2) have outlined the role of swallowed topical steroids, proton pump inhibitors, and structured elimination diets for the management of EoE, but not that of a recently approved biologic therapy. While guidelines can help reduce clinical ambiguity and aid in decision-making, these recommendations alone are insufficient to motivate practice change or generate measurable improvement in patient outcomes (3). Instead, quality metrics can promote high-quality care by providing data collection structure, formal measurement processes, and increased accountability.

The management of EoE is variable (4), potentially negatively affecting outcomes (5). Therefore, quality indicators (QI) are needed to establish paradigms of high-quality care in EoE, which will reinforce practice standardization with the intention to improve outcomes.

METHODS

To develop QI specific for patients with EoE managed by adult gastroenterologists, we used RAND/University of California, Los Angeles Appropriate Methodology (RAM) through a modified, three-round Delphi process. This study was approved by the Duke University Institutional Review Board.

Potential EoE QI were identified through extensive literature review and assessment of published professional society guidelines, encompassing initial diagnosis, management/ treatment options, and maintenance of care. A panel of esophagologists was recruited by email invitation based on expertise (see Appendix 1, Supplementary Digital Content, http://links.lww.com/AJG/C836). Analysis was performed using scoring definitions applied in established QI development (6). For a QI to be considered highly valid, each had to achieve 80% of scores within the three-point range between 7 and 9; otherwise, it had either mixed

or no agreement, the latter resulting in removal of the proposed indicator. To assess for the presence of suspected or known variability in care, experts also rated whether such quality gaps exist for each QI statement. Definitions were provided on each category for ranking indicators (Figures 1 and 2).

In *round 1*, panelists independently ranked all statements. Subsequently, panelists had the opportunity to suggest modifications to the proposed indicator to improve potential validity and were invited to participate in a real-time virtual discussion (*round 2*). Experts were encouraged to provide modifications to wording and sentence structure that would be considered in the final round. All proposed indicators had mixed agreement after *round 1* and were modified based on suggested changes by the panelists. In *round 3*, panelists reranked each modified indicator, which served as the final assessment of validity. Given the intended use of QI to reduce variation in care and drive overall improvement, we also assessed whether potential quality gaps exist for each indicator concept through a fifth category of quality gap/variation in care, as outlined in best practices for quality metric development (7). Summary statistics were performed, and valid indicators were compiled to develop the final list of EoE QI.

RESULTS

There were 9 esophageal experts who participated in the 3-round Delphi process. These panelists ranked 29 indicator statements and agreed on 9 (31%) as highly valid QI, spanning the domains of tissue sampling, endoscopic assessment and dilation, therapeutic maintenance and disease monitoring, and allergy testing (Figure 1). Within the group of valid indicators, 2 (22%) of 9 were rated as having a known or suspected quality gap. Among all QI statements evaluated, 20 (69%) did not reach sufficient validity (Figure 2), comprising the domains of dietary elimination approaches, patient symptom monitoring, and work-up approaches. Two (10%) of these statements had no agreement, and 7 (35%) had limited or 1–2 domains of agreement, but 11 (55%) had 3 domains of agreement and therefore had borderline consensus.

DISCUSSION

This study is the first to systematically develop comprehensive QI for gastroenterologists treating adult patients with EoE. Using an established methodology, experts independently agreed on 9 EoE QI having high validity and 2 also having known quality gaps, making them important areas to focus on future care improvement. The remaining highly valid QI reinforce established best practices but allow for interpretation.

Optimal approaches for EoE management have been outlined in guidelines and reviews (8,9). Nonetheless, clinical care delivery varies for patients with EoE. In this study, experts agreed that obtaining diagnostic biopsies in all patients with food impaction during endoscopy, if medically safe to do so, is a highly valid QI and a potential source for substantial quality improvement. Recent data suggest variable approaches in this regard (10–12); thus, care could be optimized by standardizing algorithms for gastroenterologists to perform endoscopy with biopsies during food impaction presentation or, if such patients

are discharged before endoscopy, to generate reflex referrals for follow-up. Continuing maintenance therapy was the other highly valid QI with an identified quality gap. Emphasizing educational initiatives among clinicians and presenting standardized patient materials may reduce poorer outcomes such as recrudescence if therapy is stopped and ultimately could lower the need for future dilations (5,13–15).

Nonetheless, the highly valid QI in our study do not present an algorithm encompassing the totality of EoE management, which is rapidly evolving, and therefore should not be considered a prescriptive approach. For example, the type of dilation performed can be tailored to the endoscopist's preference, expertise, and clinical context. Subsequent studies should confirm whether substantial variability is present in other QI, justifying their inclusion in future EoE quality measure sets.

This study is not without limitations. First, candidate indicators were generated by a comprehensive but not systematic review of the literature. Second, there was broad geographic representation within the United States among expert panelists but minimal international participation; all were academic gastroenterologists, which may not reflect the wider management of EoE. Although the panel did not include allergists, pediatric gastroenterologists, or those working within a community setting, it is noteworthy that the identified indicators do align with recommendations in published guidelines; however, future work in this area may benefit from a multidisciplinary group of clinicians.

In conclusion, we identified 9 QI as highly valid for the management of EoE. Future work will require testing and validation of these indicators toward an ultimate goal of improving EoE clinical outcomes.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Potential competing interests:

D.A.L. (Consultant: Allakos Pharmaceuticals, Astra Zeneca; Research Grant: Takeda Pharmaceuticals; and Advisory Board: Sanofi); A.N.K. (Advisory board: Castle Bioscience); F.O. (none to report); A.J.B. (Nutricia, Norgine, DrFalkPharma, Thelial, and SST: research; Laborie, Medtronic, Dr Falk Pharma, Alimentiv, Sanofi/ Regeneron and AstraZeneca: consulting); E.S.D. (Abbott, Abbvie, Adare/Ellodi, Aimmune, Akesobio, Alfasigma, ALK, Allakos, Amgen, Arena, Aslan, AstraZeneca, Avir, Biorasi, Calypso, Celgene/Receptos/BMS, Celldex, Eli Lilly, EsoCap, Eupraxia, Ferring, GSK, Gossamer Bio, Invena, Landos, LucidDx, Morphic, Nextstone Immunology, Nutricia, Parexel/Calyx, Phathom, Regeneron, Revolo, Robarts/Alimentiv, Salix, Sanofi, Shire/Takeda, Target RWE, and Upstream Bio: consulting; Adare/Ellodi, Allakos, Arena, AstraZeneca, GSK, Meritage, Miraca, Nutricia, Celgene/Receptos/BMS, Regeneron, Revolo, and Shire/Takeda: grant/research support; Allakos, Banner, and Holoclara: educational grant); G.W.F. (Arena: grant/research support; Allakos: grant/research support and consulting; Celgene/Bristol Myers Squibb: grant/research support and consulting; Astra Zeneca: consulting; Lucid: grant/research support and consulting; Nexstone: consulting; Phathom: consulting; Regeneron/Sanofi: grant research support and consulting; Takeda: grant/research support and consulting; Upstream Bio: consulting; N.Q.F.-B. (none to report); N.G. (consulting: Astra-Zeneca, Sanofi-Regeneron, Abbvie, BMS, Invea, and Allakos; Speakers bureau: Sanofi-Regeneron and Takeda; Royalties: Up-to-date); I.H. (Arena: consulting, grant/research support; AstraZeneca: consulting, grant/research support; BMS/Receptos: consulting; Calypso/Parexel: consulting; Ellodi/Adare: consulting and grant/research support; Esocap: consulting; Lilly: consulting; Phathom: consulting; Sanofi/Regeneron: consulting and grant/research support; Takeda/Shire: consulting, grant/research support); D.A.K. (Celgene: consulting; Regeneron: consulting; Takeda: consulting); K.P. (Alladapt: consulting; Allakos: speaking and teaching and grant/research support; AstraZeneca: advisory committees or review panels; Bristol Meyers Squibb: advisory committees or review panels and consulting; Chobani: grant/research support; Ellodi: advisory committees or review panels; Lucid: advisory committees or review panels; Medscape: advisory committees or

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	Proportion agreement with high validity						
Statement	Meaningfulness	Potential magnitude of effect	Feasibility	Applicability to gastroenterologists	Known or suspected presence of quality gaps		
In patients with esophageal dysphagia without a known etiology, a minimum of 6 biopsies from at least 2 esophageal levels should be obtained to assess for eosinophilic esophagitis.	87.5	87.5	100	100	50		
In all patients with food impaction, diagnostic biopsies should be obtained, if medically safe to do so, at the time of endoscopy.	100	100	87.5	100	87.5		
In patients with eosinophilic esophagitis starting an empiric elimination diet, allergy testing is not required to direct therapy.	100	100	87.5	100	75		
In patients with eosinophilic esophagitis with persistent symptoms despite histologic response, endoscopic dilation in patients with esophageal stricture should be performed.	100	87.5	100	100	37.5		
In patients with eosinophilic esophagitis requiring endoscopic dilation, all available dilation techniques are acceptable for use.	87.5	87.5	100	100	37.5		
In patients with eosinophilic esophagitis, biopsies should be obtained to assess	100	87.5	87.5	100	67.5		
histologic response after initiating treatment or with subsequent therapeutic changes.							
In patients with eosinophilic esophagitis undergoing endoscopy, the Eosinophilic Esophagitis Endoscopic Reference Score (EREFS) should be documented.	100	100	87.5	100	75		
In patients with eosinophilic esophagitis, maintenance therapy should be continued.	100	100	87.5	100	87.5		
In patients with eosinophilic esophagitis, routine clinical and endoscopic follow-up should continue after clinicopathologic remission is achieved.	87.5	87.5	87.5	100	75		

Figure 1.

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Statement	Meaningfulness	ement with high v Potential	Feasibility	Applicability to	
		magnitude of effect		gastroenterologists	
In patients suspected to have eosinophilic esophagitis, biopsies should be obtained from the stomach and duodenum if there are symptoms or endoscopic abnormalities	87.5	62.5	100	100	
suggestive of eosinophilic gastroenteritis. In patients suspected to have eosinophilic esophagitis, biopsies should be obtained from the stomach and duodenum if there are symptoms or endoscopic abnormalities suggestive of eosinophilic gastroenteritis.	87.5	75	100	100	
n patients with esophageal eosinophilic alternative causes besides eosinophilic esophagitis should be considered.	75	75	87.5	100	
In patients diagnosed with eosinophilic esophagitis, a referral to allergy/immunology should be considered for management of extra-	50	50	62.5	87.5	
esophageal comorbid atopic conditions. In patients with eosinophilic esophagitis, gastroenterologists should follow a quantified peak eosinophil count for establishing the diagnosis, monitoring disease, and assessing response to therapy.	100	100	75	100	
In patients with eosinophilic esophagitis, all reatment options should be discussed before initiating therapy.	100	100	75	100	
In patients with eosinophilic esophagitis who fail to respond or have inadequate response to initial treatment based on symptomatic, endoscopic, or histologic persistence, accepted alternative treatments are appropriate.	100	87.5	62.5	100	
In patients with eosinophilic esophagitis opting to undergo treatment with an elimination diet, a dietician should be consulted.	100	100	50	100	
In patients with eosinophilic esophagitis opting to undergo treatment with an elimination diet, empiric exclusion of any number of common eosinophilic esophagitis food triggers is acceptable.	62.5	62.5	50	75	
In patients with eosinophilic esophagitis opting to undergo treatment with an elimination diet, serial restriction or reintroduction should be performed to identify specific eosinophilic esophagitis food triggers.	100	87.5	62.5	87.5	
In patients with eosimophilic esophagitis, elemental diet may be considered as a treatment modality when patients fail to respond to proton pump inhibitors (PPIs), swallowed topical steroids, and a structured elimination diet.	62.5	37.5	12.5	62.5	
In patients with eosinophilic esophagitis opting to undergo treatment with a swallowed topical steroid, budesonide or fluticasone could be used.	100	75	100	100	
useo. In patients with eosinophilic esophagitis with partial histologic response to a single therapy, patients should have a pharmacological or dietary therapy added.	37.5	37.5	37.5	87.5	
In patients with eosinophilic esophagitis, initial treatment for eosinophilic esophagitis should not be with prednisone or other systemic glucocorticoids.	87.5	75	100	100	
n patients with eosinophilic esophagitis, endoscopic dilation should be used in conjunction with medical or dietary therapy.	87.5	75	75	87.5	
n patients with eosinophilic esophagitis, routine H or impedance-pH testing is not necessary to differentiate between gastroesophageal reflux isease (CERD) and eosinophilic esophagitis.	87.5	62.5	87.5	87.5	
n patients with eosinophilic esophagitis, a ransition care plan should be generated to acilitate transfer of care from pediatric to adult linicians.	100	87.5	50	100	
n patients with eosinophilic esophagitis, symptoms should be assessed using a standardized patient reported outcome score during clinical follow-up.	25	50	0	87.5	
In patients with eosinophilic esophagitis, functional luminal impedance planimetry (FLIP) can be performed to evaluate for treatment response after any therapeutic adjustment.	37.5	37.5	0	100	
In patients with eosinophilic esophagitis treated with a swallowed topical steroid, screening for steroid-related side effects is not required.	75	37.5	75	100	

Figure 2.