



Published in final edited form as:

*Dig Dis Sci.* 2017 March ; 62(3): 569–576. doi:10.1007/s10620-016-4409-6.

## The Quality of Care for Gastroesophageal Reflux Disease

Rena Yadlapati<sup>\*1</sup>, Lara Dakhoul<sup>\*2</sup>, John E. Pandolfino<sup>1</sup>, and Rajesh N. Keswani<sup>1</sup>

<sup>1</sup>Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA

<sup>2</sup>University of Illinois, Chicago/Advocate Christ Medical Center, Oak Lawn, Illinois, USA

### Understanding Healthcare Quality

Improving the quality of healthcare delivery is a cornerstone of modern medical care shared between all stakeholders. However, effectively improving quality requires both an understanding of the tenets of healthcare quality and how they relate to an individual disease process. This is especially important for common diseases, such as gastroesophageal reflux disease (GERD), where wide variations in practice exist. These variations ultimately reduce the value – often defined as outcomes divided by cost – of healthcare. Optimizing care value requires a collaborative decision-making process between physician and patient, where clinical evidence and best practice guidelines are applied.<sup>1</sup>

Quality medical care, as defined by the Institute of Medicine, is composed of six integrated components: safety, timeliness, equity (ensuring that care delivery does not vary between patients because of personal characteristics), effectiveness, efficiency, and patient-centeredness.<sup>2</sup> When volume drives payments (fee-for-service) and payment is dissociated from outcomes (as occurs in the United States), delivery of consistent high-quality medical care to all patients is challenging.<sup>3</sup> In response to rising healthcare costs without associated clinical benefit, the Institute for Healthcare Improvement translated these components of quality into the Triple Aim – 1) Improving the patient experience of care (including quality and satisfaction); 2) Improving the health of populations; and 3) Reducing the per capita cost of health care.<sup>2,3</sup> This framework is useful when contemplating individual, institutional, and/or governmental healthcare improvement efforts.

**Corresponding Author:** Rena Yadlapati, MD, Division of Gastroenterology & Hepatology, Northwestern University, 676 North St. Clair St. Suite 1400, Chicago, IL 60611, Office: (312) 926-7648, Fax: (312) 695-3999, rena.yadlapati@northwestern.edu.

<sup>\*</sup>Co-first authors

**Disclosures/Conflicts of Interest:** JEP: Consults for Covidien, Sandhill Scientific, and Given. RNK: Consults for Boston Scientific and Cook Endoscopy. The authors have no other reported disclosures or conflicts of interest.

**Writing Assistance:** None

**Author Contributions:**

*Rena Yadlapati:* Literature Review; drafting of manuscript; critical revision of the manuscript for important intellectual content; approval of final manuscript

*Lara Dakhoul:* Literature Review; drafting of manuscript; critical revision of the manuscript for important intellectual content; approval of final manuscript

*John E. Pandolfino:* Literature Review; drafting of manuscript; critical revision of the manuscript for important intellectual content; approval of final manuscript

*Rajesh N. Keswani:* Literature Review; drafting of manuscript; critical revision of the manuscript for important intellectual content; approval of final manuscript

A fundamental component of healthcare reform is encouraging the practice of evidence-based medicine, wherein, clinical decisions are informed by rigorous published research. However, the volume of clinical research and the need to translate this into best practice for an individual patient may be challenging. Thus, evidence-based medicine can be aided by automated systems that integrate clinical data with best practice and provide point-of-care decision support, potentially improving quality by reducing overuse and underuse. Thus, the development of specific quality measures (which can be integrated directly into clinical practice) is critical to current healthcare reform efforts.<sup>3</sup>

GERD is the most common ambulatory care diagnosis in the United States (US), afflicting an estimated 20-30% of the US population.<sup>4</sup> In recent years there has been increasing interest in defining and practicing high quality care for the work-up and management of GERD. However, little is known about the current state of the quality of GERD delivered or effective mechanisms to increase provider adherence to reported standards of quality GERD care. Thus, GERD serves as a useful framework to highlight the opportunities and current challenges of delivering high quality care. This manuscript focuses on the current understanding, progress, and remaining deficits related to practicing high quality GERD care, and intends to highlight areas for quality improvement in the delivery of care with GERD.

## **The Quality of Gastroesophageal Reflux Disease Care**

### **Development of Clinical Quality Metrics**

Between 2005-2015, multiple clinical guidelines from different societies were published regarding the treatment of GERD, with some guidelines providing conflicting recommendations. This “guideline overload” may obscure the aspects of care that are critical to delivery of high quality care. Distinct from guidelines, quality measures are linked to improved outcomes and reflect the highest and required quality of care. Measuring adherence to quality measures is useful to identify critical variations in practice and develop improvement strategies in order to delivery high quality care. In 2013, Yadlapati and colleagues published quality measures for GERD care based on the RAND/University of California, Los Angeles Appropriateness Method.<sup>5</sup> Fifty-two proposed quality measures in the areas of initial diagnosis and management, monitoring, further diagnostic testing, surgical therapy, non-cardiac chest pain, erosive esophagitis, and strictures/rings were reviewed and ranked in a two-round process with eight experts. In the end fifteen measures were deemed to be highly appropriate (Table 1).<sup>5</sup> These measures reflect aspects of care that should be universally delivered to all patients with typical GERD. This was an important initial step in defining quality in GERD care. It is now imperative to identify variations in GERD care, and correct practices which may require the use of provider education, clinical decision support, and/or financial penalties/incentives.

### **Initial Approach**

According to the Montreal Classification, the typical reflux syndrome of GERD is defined by troublesome heartburn or regurgitation symptoms - mild symptoms occurring 2 or more days a week or moderate/severe symptoms occurring 1 or more day a week. In the presence

of typical reflux syndrome, GERD can be diagnosed based on history alone in the absence of diagnostic testing.<sup>1</sup> In these cases, initial management relies on reviewing and eliminating modifiable factors and/or providing safe efficacious acid suppressive therapy. Although these management strategies are low cost and effective, prior studies have demonstrated that provider adherence to delivering recommendations is suboptimal.<sup>10,11</sup>

### Lifestyle Modifications

For instance, tobacco smoking cessation is associated with improvement in GERD symptoms.<sup>6,7</sup> Additionally, patients with nocturnal GERD symptoms should be advised to avoid late evening meals and elevate the head of the bed.<sup>6</sup> Importantly, reassuring patients on conservative management strategies for GERD enhances patient self-management and improves perceived symptoms.<sup>8,9</sup> Given the high prevalence of obesity in the United States<sup>12</sup>, the effect of weight loss in obese GERD patients is of particular interest. Multiple studies including a recent review by Ness-Jensen et al. and a systematic review conducted by De Groot et al. in 2009, support weight loss recommendations for obese patients with GERD. Results show that weight loss over a 6-month period is associated with a reduction in GERD symptoms in 81% of patients and with complete resolution in 65% of patients.<sup>13</sup> Thus, given its low cost and established efficacy, advising weight loss to patients with a body mass index of 25 or greater is considered to be a highly appropriate quality measure for GERD.<sup>5</sup> Bypassing lifestyle modifications for pharmacologic interventions or endoscopic therapy contributes to increased healthcare costs. However, multiple existing barriers prevent adherence to advising lifestyle interventions. It is well-established that, within primary care, there is insufficient time for providers to deliver all preventive care.<sup>14</sup> Furthermore, due to the complexity of care, providers may not recall all recommended interventions during a visit; this has led to a rise in clinical decision support in which the electronic health record augments care by issuing reminders. Thus, a durable model to implement lifestyle interventions should incorporate non-physician clinicians and health care informatics, and studies examining the optimal mechanism to provide lifestyle modification counseling are needed.<sup>15</sup>

**Medical Therapy**—Numerous medications are available to manage GERD including antacids, H2 receptor antagonists (H2RAs) and proton pump inhibitors (PPIs).<sup>16</sup> Among these medications, PPIs are the most commonly used pharmacological treatment for GERD due to their potent acid suppression.<sup>17</sup> However, there is increasing evidence of PPI overuse with patients remaining on these medications indefinitely, often without clear indication. In addition, there are rising concerns of potential adverse outcomes related to long-term PPI therapy.<sup>18</sup> To minimize medication overuse, clinicians should address two questions for patients on acid suppressive therapy: 1) Does my patient on acid suppressive therapy actually have GERD; and 2) Is my patient on the lowest medication dose needed to control GERD symptoms?

Up to 50% of patients with GERD symptoms may not respond to double-dose PPI therapy; this group represents a major healthcare burden and are referred to as PPI non-responders. Unfortunately, many PPI non-responders remain on long-term PPI therapy inappropriately.

In a study of 90 PPI non-responders with negative pH testing, Gawron, et al. found that 42% of patients reported continued PPI use, with one-third on double-dose PPI and less than one-fifth instructed to discontinue PPI therapy after their negative pH study.<sup>19</sup> Symptom manifestation in PPI nonresponders without abnormal esophageal acid exposure may be related to esophageal hypersensitivity, functional heartburn, or other esophageal disorders such as rumination syndrome. As such, therapy and work-up should be tailored to these mechanisms outside of GERD since PPI therapy may not provide therapeutic benefit. For instance, patients with a component of esophageal hypersensitivity/hypervigilance or functional heartburn should receive training on diaphragmatic breathing given its reported improvement in pH-metry, quality of life, and PPI requirement in a prior randomized controlled trial.<sup>2</sup>

In patients deemed to be PPI responders, it is important to ensure that the lowest dose necessary is prescribed to control symptoms. Prior studies have shown that when utilizing a structured PPI step-down therapy protocol, a majority of patients are able to reduce PPI usage resulting in significant cost savings, without adversely affecting quality of life.<sup>20,21</sup> However, outside of similar research studies, there is little standardization to ensuring that the lowest dose is achieved. Thus, adherence and follow-up of response to PPI therapy at 4 to 8 weeks following PPI initiation and titrating PPI therapy to the lowest efficacious dose and frequency are highly-appropriate quality measures for GERD.<sup>5</sup> Unfortunately, implementation of this measure does not occur in many patients.<sup>22</sup>

In summary, it is imperative that patients who are begun on empiric pharmacologic therapy for suspected GERD receive appropriate follow-up to assess treatment response. Mechanisms to streamline management algorithms for PPI responders (to titrate to lowest effective dose) and PPI non-responders (to stop PPI and change therapy) are required in order to deliver high quality efficient care without delays.

### Other considerations

A high quality approach should consider additional factors that may increase the predilection to develop GERD. For instance, several over-the-counter and prescription medications have been linked to GERD. Three different underlying mechanisms have been implicated: relaxation of the lower esophageal sphincter, increasing esophageal inflammation or slowing digestion. The most common culprit medications are: antibiotics, antidepressants, narcotics, bisphosphonates and non-steroidal anti-inflammatory drugs.<sup>3</sup> While a specific diet has not been shown to cause GERD, patients should be instructed to avoid foods that trigger their particular symptoms. In Asian populations *Helicobacter Pylori* is considered one of the risk factors for GERD; however, its eradication has no significant effect on the occurrence of GERD in the long term. As a result, empiric screening for *H. pylori* is not routinely recommended and should be decided according to patients' individual conditions.<sup>4, 5</sup>

## Diagnostic Testing and Endoscopic Interventions

### Endoscopic overuse

Endoscopy is increasingly utilized for evaluation of gastrointestinal symptoms, and data from the Centers for Medicare & Medicaid Services over the past decade demonstrate a greater than 40% increase in upper endoscopy utilization.<sup>23</sup> Moreover, there are concerns that 10 to 40% of upper endoscopies are performed without appropriate indication.<sup>24</sup> Thus, inappropriate utilization of upper endoscopy is a major healthcare issue. With regards to GERD, quality measures<sup>25</sup> and guidelines recommend endoscopic evaluation in the presence of alarm symptoms or in PPI non-responders to identify alternative disorders, evidence of erosive disease, or to consider wireless reflux testing.<sup>5,26,27</sup> However, it is clear that upper endoscopy is overutilized in low-risk GERD patients, further contributing to healthcare costs.<sup>28</sup>

There are numerous potential contributors to this suspected upper endoscopy overuse, including fear of medicolegal liability, financial incentives, and patient/caregiver expectations.<sup>24</sup> As payment reform evolves in the United States, performing endoscopies without appropriate indication will no longer be financially lucrative, and may in fact adversely impact finances. In preparation, institutions should examine appropriateness to monitor procedural indications and identify areas for improvement.

### Ambulatory esophageal pH monitoring

The current gold standard for evaluating abnormal esophageal acid exposure is ambulatory esophageal pH monitoring.<sup>29</sup> Per the American College of Gastroenterology practice guidelines, esophageal pH monitoring is useful: 1) to document abnormal esophageal acid exposure in an endoscopy-negative patient being considered for endoscopic or surgical antireflux procedure, and 2) in the evaluation of an endoscopy-negative patient with typical reflux symptoms refractory to PPI therapy.<sup>30</sup> Over the past decade, there have been multiple technological advancements in pH monitoring, each with its own important role. pH-impedance monitoring can detect non-acidic reflux and directionality of reflux, and reliably discriminate between behavioral syndromes such as rumination and belching disorders from GERD.<sup>6</sup> However, there is limited data on the prognostic utility of impedance monitoring in patients undergoing evaluation for anti-reflux surgery.<sup>7-10</sup> Wireless pH monitoring facilitates prolonged monitoring for up to 96 hours without a transnasal catheter, and may increase the sensitivity of reflux detection.<sup>11, 12</sup> Currently the optimal diagnostic strategies utilizing pH monitoring remains an area of substantial controversy amongst clinicians. Questions regarding which tool is the better technology, whether the study protocol should be on or off PPI therapy, and which metrics and associated cut-offs to use in interpretation remain unanswered. Consequently, during a process to identify quality measures for GERD, there were several issues and disagreement amongst experts related to pH monitoring.<sup>5</sup>

The lack of consensus translates to inappropriate utilization of pH monitoring. In a prospective multicenter study done in Italy and published in 2004, only 323 examinations (38%) performed were for appropriate indications, and the vast majority for pH monitoring indications were inconsistent with the guidelines.<sup>31</sup> In contrast, Ali, et al. found that that pH

monitoring is underutilized in the evaluation of persistent GERD symptoms after anti-reflux surgery.<sup>32</sup>

These barriers impart a major health care burden, since up to 50% of patients with GERD do not respond to PPI therapy optimization and require further workup with pH monitoring. Importantly, appropriate utilization of ambulatory pH monitoring would prevent unnecessary treatment with acid-reducing medications as well as costly endoscopic and surgical interventions. Thus, research is needed to develop a high-quality standard approach to reflux monitoring, with specific clarification in technology, metric interpretation, lifestyle/dietary protocol during monitoring, and management approaches based on results.<sup>30</sup>

## Non-Pharmacologic Anti-Reflux Therapies

Non-pharmacologic anti-reflux management for GERD may be indicated in PPI nonresponsive GERD with evidence of pathologic esophageal acid exposure, disrupted anti-reflux barrier and large hiatal hernia. Laparoscopic Nissen fundoplication (LNF) remains the current gold standard anti-reflux procedure.<sup>33</sup> There are however concerns about the safety and post-operative outcomes of LNF. For instance, a large retrospective analysis demonstrated significantly greater incidence of perforations at low-volume centers compared to high-volume centers.<sup>34</sup> Recently, initiatives through the American College of Surgeons National Surgical Quality Improvement Program to improve surgery-related patient safety and health care quality have expanded rapidly.<sup>35,36</sup> However, despite the growth in public reporting of surgical outcomes and health care quality data,<sup>36</sup> data regarding anti-reflux procedures is not widely available. Consequently, there is considerable uncertainty about how to best measure and improve quality for anti-reflux surgery. Unanswered questions include: standardization of patient selection, relevant patient reported outcomes, institutional skill, training composition, competency assessment, and recommended procedure volume. A lack of available high-quality data regarding surgical outcomes serves as a critical impediment to defining quality measures for anti-reflux surgery. This was highlighted in a recent Cochrane systematic review comparing outcomes between LNF and medical treatment, which in the end only included four studies and even then the quality of evidence was low or very low.<sup>37</sup> Other reports have also presented conflicting results from trials comparing antireflux surgery and PPIs.<sup>38</sup> The development of quality measures for GERD also reflected the critical deficiency of evidence or consensus, and thus the panel did not review measures related to anti-reflux surgery.<sup>5</sup>

There are limited data on the economic value of anti-reflux surgery when compared to other management options for GERD. Gawron et al. performed a systematic review of economic evaluations and cost studies of GERD management strategies, reporting that surgery may be cost effective compared to long term PPI therapy in patients with chronic GERD symptoms at a time horizon of 3-10 years.<sup>16</sup> Still, treatment failures are inevitable regardless of whether medical PPI therapy or anti-reflux surgery is chosen.<sup>38</sup> In recent years, refinements to older techniques have renewed enthusiasm for alternative anti-reflux procedures including targeted radiofrequency energy delivery to the esophagogastric junction, endoscopic fundoplication, magnetic sphincter augmentation and electrical stimulation of the lower esophageal sphincter. Trials examining the long-term outcomes of these endoscopic anti-



reflux options are underway and will also help to clarify their efficacy compared to surgical or medical options.<sup>39</sup> Currently, to aid informed decision making by payers, policy makers, clinicians, and patients alike, there is an urgent need for a large, randomized, well-designed, controlled trial to conclusively address the efficacy of anti-reflux therapies for the management of GERD.<sup>40</sup>

Based on current opinion, an overall value-based model to anti-reflux procedures should involve a multidisciplinary approach involving the patient, the primary care physician, the gastroenterologist and the surgeon. Although laparoscopic anti-reflux surgery is considered safe when performed by experienced surgeons,<sup>41</sup> a careful discussion should focus on balancing the risks and benefits of medical, endoscopic and surgical options. In addition, pre-procedural discussions should involve setting patient expectations, evaluating candidacy, and discussing strategies to increase postoperative effectiveness. All patients considering invasive anti-reflux therapy should have attempted weight loss if overweight and aforementioned lifestyle modifications. While robust patient reported outcomes data is not available, a study of patients referred for laparoscopic anti-reflux surgery found that leading expectations included: symptom (heartburn and regurgitation) abatement (92.8%), return to normal daily activities (84.3%), improvement in quality of life (72.9%), successful procedure without complication or side effects (52.9%), and protection from Barrett's esophagus or cancer (48.6%).<sup>42</sup> A minority valued normalization of acid exposure or healing of esophagitis. These can serve as a framework for creating a patient centered, outcomes driven value based model to anti-reflux surgery for GERD.<sup>42</sup>

## Extraesophageal Reflux

While chronic cough, laryngeal complaints and dental erosions are increasingly associated with GERD,<sup>43</sup> the true relationship between gastroesophageal reflux and extraesophageal symptoms is unknown.<sup>44</sup> Consequently, in the first year of presentation, patients with extraesophageal symptoms undergo an average of 6.4 diagnostic procedures and visit with 10 consultants. The mean direct cost of working-up and managing a patient with extraesophageal reflux is estimated to be \$5,438 in the first year alone, 5.6 times the annual cost of typical GERD.<sup>45,46</sup> Empiric PPI trials largely contribute to this healthcare expenditure, although up to 50% of patients will not manifest a symptom response as the therapeutic benefits of PPI are comparable to placebo.<sup>47-50</sup> The diagnostic tools for extraesophageal symptoms are also limited. Laryngoscopy has poor specificity and inter-rater reliability, esophageal pH monitoring is poorly sensitive, and a minority of patients will have abnormal findings on upper endoscopy.<sup>51</sup> The clinical role of novel technologies such as oropharyngeal pH monitoring and salivary pepsin analysis is also unclear given lack of validated normative thresholds and mixed reports in the literature.<sup>51,52</sup> Unlike typical GERD, the lack of substantiated high quality evidence supporting an approach for extraesophageal reflux hinders the ability to develop a value-based approach to evaluating and managing extraesophageal reflux; and, further studies are critically needed to address these barriers. At this time, best practice approaches should consider non-esophageal processes such as environmental exposure, sleep apnea, medication effect, and primary sinus or pulmonary conditions in the evaluation of chronic cough, sinus symptoms, dental erosions and laryngeal complaints. In the setting of concurrent typical GERD symptoms, it is

reasonable to initiate an empiric PPI trial, understanding that all patients initiated on empiric PPI therapy should receive follow-up within eight weeks to assess response. Similar to the approach for typical GERD, patients who respond to PPI therapy should be titrated to the lowest most efficacious PPI dose whereas those who do not respond should undergo work-up to evaluate whether there is evidence of abnormal esophageal acid exposure and to explore other etiologies.<sup>46</sup>

## The Future

Practitioners caring for patients with GERD have made nascent steps towards improving the quality of care - particularly defining aspects of high quality initial work-up, pharmacologic management, and appropriate use of EGD. However, critical work is still required to seamlessly implement these best practices and quality measures into practice with resultant improved clinical outcomes. In addition, there remain many knowledge gaps regarding endoscopic and surgical anti-reflux techniques, reflux testing, and the approach to extraesophageal symptoms. Optimal GERD management will increasingly require an emphasis on care coordination, involving health care workers from different professions and subspecialties.<sup>53</sup> Once the most important residual barriers are identified, our healthcare system must prioritize focus on improving quality to create a patient-centered and value-based approach to GERD.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

**Grant Support:** RY: Supported by NIH T32DK101363

## Abbreviations

<b>GERD</b>	Gastroesophageal reflux disease
<b>US</b>	United States
<b>H2RAs</b>	H2 receptor antagonists
<b>PPIs</b>	Proton pump inhibitors
<b>GI</b>	gastrointestinal
<b>LNF</b>	Laparoscopic Nissen fundoplication

## References

1. Blumenthal D, McGinnis JM. Measuring Vital Signs: an IOM report on core metrics for health and health care progress. *JAMA*. 2015; 313(19):1901–1902. DOI: 10.1001/jama.2015.4862 [PubMed: 25919301]
2. Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Committee on Quality of Health Care in America. 2001. ISBN <http://books.google.com/books?id=Xd1pAAAAMAJ&q=crossing+the+quality+chasm+a+new+health+system+for+the+21st>



+century&dq=crossing+the+quality+chasm+a+a+new+health+system+for+the+21st  
+century&pgis=1&pgis=1

3. Manchikanti L, Caraway DL, Parr AT, Fellows B, Hirsch JA. Patient Protection and Affordable Care Act of 2010: reforming the health care reform for the new decade. *Pain Physician*. 14(1):E35–E67. <http://www.ncbi.nlm.nih.gov/pubmed/21267047>.
4. Jaspersen D. Extraesophageal manifestations in gastroesophageal reflux disease. *Minerva Gastroenterol Dietol*. 2006; 52(3):269–274. <http://www.ncbi.nlm.nih.gov/pubmed/16971871>. [PubMed: 16971871]
5. Yadlapati R, Gawron AJ, Bilimoria K, et al. Development of quality measures for the care of patients with gastroesophageal reflux disease. *Clin Gastroenterol Hepatol*. 2015; 13(5):874–883 e2. DOI: 10.1016/j.cgh.2014.11.012 [PubMed: 25460560]
6. Ness-Jensen E, Hveem K, El-Serag H, Lagergren J. Lifestyle Intervention in Gastroesophageal Reflux Disease. *Clin Gastroenterol Hepatol*. 2016; 14(2):175–182 e3. DOI: 10.1016/j.cgh.2015.04.176 [PubMed: 25956834]
7. De Groot NL, Burgerhart JS, Van De Meeberg PC, de Vries DR, Smout AJPM, Siersema PD. Systematic review: the effects of conservative and surgical treatment for obesity on gastro-oesophageal reflux disease. *Aliment Pharmacol Ther*. 2009; 30(11-12):1091–1102. DOI: 10.1111/j.1365-2036.2009.04146.x [PubMed: 19758397]
8. Finley K, Giannamore M, Bennett M, Hall L. Assessing the impact of lifestyle modification education on knowledge and behavior changes in gastroesophageal reflux disease patients on proton pump inhibitors. *J Am Pharm Assoc*. 2003; 49(4):544–548. DOI: 10.1331/JAPhA.2009.08004
9. Dibley LB, Norton C, Jones R. Non-pharmacological intervention for gastro-oesophageal reflux disease in primary care. *Br J Gen Pract*. 2010; 60(581):e459–e465. DOI: 10.3399/bjgp10X544050 [PubMed: 21144190]
10. Salyers WJ, Mansour A, El-Haddad B, Golbeck AL, Kallail KJ. Lifestyle modification counseling in patients with gastroesophageal reflux disease. *Gastroenterol Nurs*. 30(4):302–304. DOI: 10.1097/01.SGA.0000287204.44226.7e
11. Blair DI, Kaplan B, Spiegler J. Patient characteristics and lifestyle recommendations in the treatment of gastroesophageal reflux disease. *J Fam Pract*. 1997; 44(3):266–272. <http://www.ncbi.nlm.nih.gov/pubmed/9071246>. [PubMed: 9071246]
12. Johnson NB, Hayes LD, Brown K, Hoo EC, Ethier KA, Centers for Disease Control and Prevention (CDC). CDC National Health Report: leading causes of morbidity and mortality and associated behavioral risk and protective factors—United States, 2005–2013. *MMWR Suppl*. 2014; 63(4):3–27. <http://www.ncbi.nlm.nih.gov/pubmed/25356673>.
13. Singh M, Lee J, Gupta N, et al. Weight loss can lead to resolution of gastroesophageal reflux disease symptoms: a prospective intervention trial. *Obesity (Silver Spring)*. 2013; 21(2):284–290. DOI: 10.1002/oby.20279 [PubMed: 23532991]
14. Yarnall KSH, Pollak KI, Østbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention? *Am J Public Health*. 2003; 93(4):635–641. <http://www.ncbi.nlm.nih.gov/pubmed/12660210>. [PubMed: 12660210]
15. Eherer A. Management of gastroesophageal reflux disease: lifestyle modification and alternative approaches. *Dig Dis*. 2014; 32(1-2):149–151. DOI: 10.1159/000357181 [PubMed: 24603400]
16. Gawron AJ, French DD, Pandolfino JE, Howden CW. Economic evaluations of gastroesophageal reflux disease medical management. *Pharmacoeconomics*. 2014; 32(8):745–758. DOI: 10.1007/s40273-014-0164-8 [PubMed: 24807469]
17. Chey WD, Mody RR, Wu EQ, et al. Treatment patterns and symptom control in patients with GERD: US community-based survey. *Curr Med Res Opin*. 2009; 25(8):1869–1878. DOI: 10.1185/03007990903035745 [PubMed: 19530980]
18. Gomm W, von Holt K, Thomé F, et al. Association of Proton Pump Inhibitors With Risk of Dementia: A Pharmacoepidemiological Claims Data Analysis. *JAMA Neurol*. Feb.2016 doi: 10.1001/jamaneurol.2015.4791
19. Gawron AJ, Rothe J, Fought AJ, et al. Many patients continue using proton pump inhibitors after negative results from tests for reflux disease. *Clin Gastroenterol Hepatol*. 2012; 10(6):620–625. quiz e57. DOI: 10.1016/j.cgh.2012.02.012 [PubMed: 22366177]

20. Inadomi JM, Jamal R, Murata GH, et al. Step-down management of gastroesophageal reflux disease. *Gastroenterology*. 2001; 121(5):1095–1100. <http://www.ncbi.nlm.nih.gov/pubmed/11677201>. [PubMed: 11677201]
21. Coté GA, Ferreira MR, Rozenberg-Ben-Dror K, Howden CW. Programme of stepping down from twice daily proton pump inhibitor therapy for symptomatic gastro-oesophageal reflux disease associated with a formulary change at a VA medical center. *Aliment Pharmacol Ther*. 2007; 25(6): 709–714. DOI: 10.1111/j.1365-2036.2007.03248.x [PubMed: 17311604]
22. Gawron AJ, Pandolfino JE. Ambulatory Reflux Monitoring in GERD – Which Test Should be Performed and Should Therapy be Stopped? *Curr Gastroenterol Rep*. 2013; 15(4):316.doi: 10.1007/s11894-013-0316-6 [PubMed: 23475599]
23. Shaheen NJ, Weinberg DS, Denberg TD, et al. Upper endoscopy for gastroesophageal reflux disease: best practice advice from the clinical guidelines committee of the American College of Physicians. *Ann Intern Med*. 2012; 157(11):808–816. DOI: 10.7326/0003-4819-157-11-201212040-00008 [PubMed: 23208168]
24. Zamosky L. GERD: rising healthcare costs spark new debate, guidelines. Revised standards designed to save system money, prevent overuse of diagnostics. *Med Econ*. 2013; 90(10):48–50. 54. <http://www.ncbi.nlm.nih.gov/pubmed/24063125>.
25. Park WG, Shaheen NJ, Cohen J, et al. Quality indicators for EGD. *Gastrointest Endosc*. 2015; 81(1):17–30. DOI: 10.1016/j.gie.2014.07.057 [PubMed: 25480101]
26. Kahrilas PJ, Shaheen NJ, Vaezi MF, American Gastroenterological Association Institute, Clinical Practice and Quality Management Committee. American Gastroenterological Association Institute technical review on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008; 135(4):1392–1413. 1413.e1–e5. DOI: 10.1053/j.gastro.2008.08.044 [PubMed: 18801365]
27. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. 2013; 108(3):308–328. quiz 329. DOI: 10.1038/ajg.2012.444 [PubMed: 23419381]
28. Allen JI. Endoscopy for gastroesophageal reflux disease: choose wisely. *Ann Intern Med*. 2012; 157(11):827–828. DOI: 10.7326/0003-4819-157-11-201212040-00015 [PubMed: 23208171]
29. Kleiman DA, Zarnegar R. An old tool may fix a new problem: early utilization of 24-h esophageal pH monitoring may reduce unnecessary proton-pump inhibitor use and improve outcomes. *J Comp Eff Res*. 2013; 2(5):409–411. DOI: 10.2217/ceer.13.60 [PubMed: 24236735]
30. Hirano I, Richter JE, Practice Parameters Committee of the American College of Gastroenterology. ACG practice guidelines: esophageal reflux testing. *Am J Gastroenterol*. 2007; 102(3):668–685. DOI: 10.1111/j.1572-0241.2006.00936.x [PubMed: 17335450]
31. Radaelli F, Strocchi E, Passaretti S, et al. Is esophageal pH monitoring used appropriately in an open-access system? A prospective multicenter study. *Am J Gastroenterol*. 2004; 99(11):2115–2120. DOI: 10.1111/j.1572-0241.2004.40175.x [PubMed: 15554989]
32. Ali MA, Lacy BE. Esophageal manometry and pH monitoring: gastroenterologists' adherence to published guidelines. *J Clin Gastroenterol*. 2005; 39(7):584–590. <http://www.ncbi.nlm.nih.gov/pubmed/16000925>. [PubMed: 16000925]
33. Ashfaq A. Revision of failed transoral incisionless fundoplication by subsequent laparoscopic Nissen fundoplication. *World J Gastroenterol*. 2014; 20(45):17115.doi: 10.3748/wjg.v20.i45.17115 [PubMed: 25493024]
34. Varban OA, McCoy TP, Westcott C. A comparison of pre-operative comorbidities and post-operative outcomes among patients undergoing laparoscopic nissen fundoplication at high- and low-volume centers. *J Gastrointest Surg*. 2011; 15(7):1121–1127. DOI: 10.1007/s11605-011-1492-z [PubMed: 21557016]
35. Ingraham AM, Richards KE, Hall BL, Ko CY. Quality improvement in surgery: the American College of Surgeons National Surgical Quality Improvement Program approach. *Adv Surg*. 2010; 44:251–267. <http://www.ncbi.nlm.nih.gov/pubmed/20919525>. [PubMed: 20919525]
36. Sherman KL, Gordon EJ, Mahvi DM, et al. Surgeons' perceptions of public reporting of hospital and individual surgeon quality. *Med Care*. 2013; 51(12):1069–1075. DOI: 10.1097/MLR.000000000000013 [PubMed: 24226305]

37. Garg SK, Gurusamy KS. Laparoscopic fundoplication surgery versus medical management for gastro-oesophageal reflux disease (GORD) in adults. *Cochrane database Syst Rev.* 2015; 11:CD003243.doi: 10.1002/14651858.CD003243.pub3
38. Lundell L. Borderline indications and selection of gastroesophageal reflux disease patients: "Is surgery better than medical therapy"? *Dig Dis.* 2014; 32(1-2):152–155. DOI: 10.1159/000357182 [PubMed: 24603401]
39. Maradey-Romero C, Kale H, Fass R. Nonmedical therapeutic strategies for nonerosive reflux disease. *J Clin Gastroenterol.* 2014; 48(7):584–589. DOI: 10.1097/MCG.0000000000000125 [PubMed: 25000345]
40. Lipka S, Kumar A, Richter JE. No evidence for efficacy of radiofrequency ablation for treatment of gastroesophageal reflux disease: a systematic review and meta-analysis. *Clin Gastroenterol Hepatol.* 2015; 13(6):1058–1067.e1. DOI: 10.1016/j.cgh.2014.10.013 [PubMed: 25459556]
41. Richter JE. Gastroesophageal reflux disease treatment: side effects and complications of fundoplication. *Clin Gastroenterol Hepatol.* 2013; 11(5):465–471. quiz e39. DOI: 10.1016/j.cgh.2012.12.006 [PubMed: 23267868]
42. Kamolz T, Pointner R. Expectations of patients with gastroesophageal reflux disease for the outcome of laparoscopic antireflux surgery. *Surg Laparosc Endosc Percutan Tech.* 2002; 12(6): 389–392. <http://www.ncbi.nlm.nih.gov/pubmed/12496543>. [PubMed: 12496543]
43. Vakil N, van Zanten SV, Kahrilas P, Dent J, Jones R, Global Consensus Group. The Montreal definition and classification of gastroesophageal reflux disease: a global evidence-based consensus. *Am J Gastroenterol.* 2006; 101(8):1900–1920. quiz 1943. DOI: 10.1111/j.1572-0241.2006.00630.x [PubMed: 16928254]
44. Stanghellini V, Armstrong D, Mönnikes H, Berghöfer P, Gatz G, Bardhan KD. Determination of ReQuest-based symptom thresholds to define symptom relief in GERD clinical studies. *Digestion.* 2007; 75(Suppl 1):55–61. DOI: 10.1159/000101083 [PubMed: 17489033]
45. Francis DO, Rymer JA, Slaughter JC, et al. High economic burden of caring for patients with suspected extraesophageal reflux. *Am J Gastroenterol.* 2013; 108(6):905–911. DOI: 10.1038/ajg.2013.69 [PubMed: 23545710]
46. Fenter TC, Naslund MJ, Shah MB, Eaddy MT, Black L. The cost of treating the 10 most prevalent diseases in men 50 years of age or older. *Am J Manag Care.* 2006; 12(4 Suppl):S90–S98. <http://www.ncbi.nlm.nih.gov/pubmed/16551207>. [PubMed: 16551207]
47. Noordzij JP, Khidr A, Evans BA, et al. Evaluation of omeprazole in the treatment of reflux laryngitis: a prospective, placebo-controlled, randomized, double-blind study. *Laryngoscope.* 2001; 111(12):2147–2151. DOI: 10.1097/00005537-200112000-00013 [PubMed: 11802014]
48. El-Serag HB, Lee P, Buchner A, Inadomi JM, Gavin M, McCarthy DM. Lansoprazole treatment of patients with chronic idiopathic laryngitis: a placebo-controlled trial. *Am J Gastroenterol.* 2001; 96(4):979–983. DOI: 10.1111/j.1572-0241.2001.03681.x [PubMed: 11316215]
49. Steward DL, Wilson KM, Kelly DH, et al. Proton pump inhibitor therapy for chronic laryngopharyngitis: a randomized placebo-control trial. *Otolaryngol Head Neck Surg.* 2004; 131(4):342–350. DOI: 10.1016/j.otohns.2004.03.037 [PubMed: 15467597]
50. Hom C, Vaezi MF. Extraesophageal manifestations of gastroesophageal reflux disease. *Gastroenterol Clin North Am.* 2013; 42(1):71–91. DOI: 10.1016/j.gtc.2012.11.004 [PubMed: 23452632]
51. Yadlapati R, Adkins C, Jaiyeola D-M, et al. Abilities of Oropharyngeal pH Tests and Salivary Pepsin Analysis to Discriminate Between Asymptomatic Volunteers and Subjects with Symptoms of Laryngeal Irritation. *Clin Gastroenterol Hepatol.* Dec.2015 doi: 10.1016/j.cgh.2015.11.017
52. Yadlapati R, Pandolfino JE, Lidder AK, et al. Oropharyngeal pH Testing Does Not Predict Response to Proton Pump Inhibitor Therapy in Patients with Laryngeal Symptoms. *Am J Gastroenterol.* Apr.2016 doi: 10.1038/ajg.2016.145
53. Armstrong D, Marshall JK, Chiba N, et al. Canadian Consensus Conference on the management of gastroesophageal reflux disease in adults - update 2004. *Can J Gastroenterol.* 2005; 19(1):15–35. <http://www.ncbi.nlm.nih.gov/pubmed/15685294>. [PubMed: 15685294]

**Clinical strategies to improve the quality of the management of GERD**

1. Develop multidisciplinary electronic mechanisms to provide lifestyle modification counseling
2. Develop PPI monitoring programs to assess adherence and symptom response at 4 to 8 weeks and decrease PPI doses to the lowest effective dose.
3. Integrate cognitive behavioral strategies and diaphragmatic breathing for patients with a component of esophageal hypersensitivity/hypervigilance or functional heartburn

**Steps needed to improve diagnostic testing utilization**

1. Institutions should examine the appropriateness of procedural indications related to GERD
2. Research is needed to develop a high-quality standard approach to reflux monitoring, with specific clarification in technology, metric interpretation, lifestyle/dietary protocol during monitoring, and management approaches based on results

**Table 1**

## High-validity GERD Care Quality Measures

Initial diagnosis and management (n = 7)	<ul style="list-style-type: none"> <li>-If a patient has typical GERD, then an initial trial of empirical PPI therapy, H<sub>2</sub> RA, or antacid is appropriate.</li> <li>-If PPI therapy is initiated, then it should be at once-a-day dosing before the first meal of the day (or before an evening meal for patients with predominant nighttime symptoms).</li> <li>-If a patient with a diagnosis of GERD is seen for initial evaluation, then the patient should be assessed for the presence or absence of the following alarm symptoms: involuntary weight loss, dysphagia, and GI bleeding.</li> <li>-If a patient with a diagnosis of GERD has at least 1 alarm symptom, then upper endoscopy should be performed.</li> <li>-If a patient with GERD is overweight or obese, then weight loss should be advised.</li> <li>-If a patient with GERD has an endoscopy report that indicates a suspicion of Barrett's esophagus, then suspicious areas should be biopsied.</li> <li>-If a patient with GERD has troublesome dysphagia, then endoscopy with biopsy should be performed. Biopsies should target any areas of suspected metaplasia, dysplasia, or, in the absence of visual abnormalities, normal mucosa (4 biopsies from both proximal and distal esophagus to rule out eosinophilic esophagitis).</li> </ul>
Monitoring (n = 2)	<ul style="list-style-type: none"> <li>-If a patient with GERD is prescribed chronic PPI or H<sub>2</sub> RAs, then the patient should receive an assessment of their GERD symptoms within 12 months.</li> <li>-If a patient with GERD is prescribed an initial empirical trial of PPI, then the patient should have scheduled follow-up within 4 to 12 weeks.</li> </ul>
PPI-refractory symptoms (n = 1)	<ul style="list-style-type: none"> <li>-If a patient has refractory typical GERD symptoms despite twice-daily PPI and adherence to PPI, then an upper endoscopy should be performed to exclude non-GERD etiologies.</li> </ul>
Chest pain (n = 1)	<ul style="list-style-type: none"> <li>-If a patient has chest pain, then a cardiac cause should be excluded before the commencement of a gastrointestinal evaluation.</li> </ul>
Erosive esophagitis (n = 3)	<ul style="list-style-type: none"> <li>-If erosive esophagitis is seen on endoscopy, then findings should be classified according to the LA classification system.</li> <li>-If a patient has LA grade B or greater erosive esophagitis, then at least an 8-week course of PPI is the therapy of choice for symptom relief and healing.</li> <li>-If a patient has LA grade C or D erosive esophagitis, then repeat endoscopy should be performed after a course of antisecretory therapy to exclude underlying Barrett's esophagus.</li> </ul>
Stricture/ring (n = 1)	<ul style="list-style-type: none"> <li>-If a patient has a peptic stricture, then maintenance PPI therapy is recommended after stricture dilation to reduce the need for repeated dilations.</li> </ul>

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript