Identifying Barrett's Esophagus Risk

in a Primary Care Setting

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Abstract

Barrett's esophagus incidence has been on the rise for the past four decades. Early identification of Barrett's esophagus is essential to preventing the morbidity and mortality associated with esophageal adenocarcinoma, a malignancy with an 18% five-year survival rate. With no national standard for screening, primary care providers must identify and refer patients who are at high risk of Barrett's esophagus for endoscopic evaluation. This quality improvement project aimed to develop a protocol to identify patients at high risk for Barrett's esophagus. Risk assessment was accomplished with a patient-completed over-the-counter medication survey and GerdQ questionnaire to identify patients with gastroesophageal reflux disease. When gastroesophageal reflux disease (GERD) was identified, providers assessed for the presence of additional Barrett's esophagus risk factors. During the 14-week implementation period, 79 patients were evaluated. Over-the-counter medications were used by 64% of patients, and 37% reported using over-the-counter reflux medication at least monthly. A diagnosis of GERD was identified in 29% of the patients. Of the 79 patients completing the tools, 62 were evaluated for Barrett's esophagus risk, with 15% identified as high risk and 6% meeting the criteria for endoscopic screening. The use of the over-the-counter survey and GerdQ questionnaire were effective for identification of Barrett's esophagus high risk in this primary care practice. Recommendations were made for the use of these tools at the time of colorectal cancer screening referral to facilitate risk assessment and concurrent referral for Barrett's esophagus screening if needed.

Key words: Barrett's esophagus, gastroesophageal reflux disease, disease risk assessment, over-the-counter medication reconciliation, GerdQ

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Chapter One: Overview of the Problem of Interest

There has been a global rise in the incidence of Barrett's esophagus (BE) over the last four decades (Runge, Abrams, & Shaheen, 2015) with a corresponding seven-fold increase in esophageal adenocarcinoma (EAC; Hang et al., 2018). BE, found primarily in the West, especially in Eastern Europe and the United States (U.S.; Kuipers & Spaander, 2018), is the precursor lesion for EAC, which has an 18% five-year survival rate (Peery et al., 2015). The diagnosis of EAC is often made after the onset of symptoms causing the five-year survival rate to remain static (Iyer & Kaul, 2019). Neither the U.S. Preventative Services Task Force (USPSTF), the American College of Gastroenterology (ACG; Shaheen, Falk, Iyer, & Gerson, 2016), nor the American Gastroenterological Association (AGA; Spechler, Sharma, Souza, Inadomi, & Shaheen, 2011) recommend global screening as it would not be cost-effective due to the relatively low incidence of BE in the general population. However, both the ACG and the AGA endorse screening patients identified as high-risk for the development of BE (Shaheen et al., 2016; Spechler et al., 2011).

Gastroesophageal reflux disease (GERD) is considered the primary risk factor for BE with the most significant risk found in those with more frequent and longer duration of symptoms (Runge et al., 2015). GERD symptom management is one of the top ten gastrointestinal (GI) reasons for ambulatory visits annually, with GERD being the second most common GI diagnosis documented in the ambulatory setting in the U.S. (Peery et al., 2019). Despite these statistics, many people remain undiagnosed due to self-treatment with readily available over-the-counter medications such as proton pump inhibitors (PPI), histamine-2 receptor antagonists (H2RA), and other antacids (Kellerman & Kintanar, 2017). The lack of communication between patients and health care providers regarding over-the-counter (OTC)

medication use is a barrier to diagnosis (Serper et al., 2013). GERD can be empirically diagnosed in the primary care setting based upon clinical presentation, or more accurately with the use of a validated questionnaire, such as the GerdQ, which provides diagnostic scoring (Gyawali et al., 2018). The GerdQ should be completed by patients previously diagnosed with GERD and those who are self-treating their symptoms to quantify the severity and impact of their disease (Gyawali et al., 2018). A risk assessment for BE will only be valid if patients with symptomatic GERD are identified (Shaheen, Falk, Iyer, & Gerson, 2016).

Background Information

Barrett's esophagus is thought to develop as part of the body's defense mechanism against continual tissue insult caused by exposure to a high acid environment (Crews et al., 2016). Identified risk factors for BE are chronic GERD, male gender, Caucasian race, age 50 years or older, central obesity, smoking, and family history of BE or esophageal cancer (Runge et al., 2015). The prevalence of BE, determined through autopsy and population-based studies, ranges from 0.5% to 2% of the general population and from 5% to 15% in those with chronic reflux symptoms (Runge et al., 2015).

Peery et al. (2019) used U.S. Cancer Statistics data from the Centers for Disease Control and Prevention (CDC) to identify GI cancer incidence, prevalence, and survival rates for the year 2014. Esophageal cancers had an incidence rate of 6.3 per 100,000 (Peery et al., 2019) with a lifetime risk of 0.5% and an 18% five-year survival rate (Peery et al., 2015). This low survival rate is due, in part, to the late identification of advanced EAC once it becomes symptomatic (Crews et al., 2016) with no improvement seen in survival rates over the past several decades (Iyer & Kaul, 2019). Of all GI-related deaths in the U.S., esophageal cancer as an underlying or contributing cause of death is ranked sixth, with a rate of 5.6/100,000 (Peery et al., 2019).

Esophageal cancer carries a heavy cost burden. Based on 2018 data, the overall annual cost of care for all patients with esophageal cancer was approximately $1.7 billion in the U.S. (National Cancer Institute, 2020). The annual cost can be broken down into phases of care with $683 million spent on initial care, $204 million for ongoing care, and $791 million for care during the last year of life (National Cancer Institute, 2020). The per diagnosis cost equates to more than $250 thousand for the first and last year of life combined for those under 65 years of age, and $184 thousand if diagnosed at age 65 or older (Mariotto, Yabroff, Shao, Feuer, & Brown, 2011).

The estimated worldwide prevalence of GERD is 13%, but this number varies geographically (Richter & Rubenstein, 2018). In the U.S., GERD prevalence is estimated between 6% and 30%, possibly due to the diversity of the population and the heterogeneity of the study tools used (Richter & Rubenstein, 2018). Kellerman and Kintanar (2017) determined a sample weighted mean for GERD in the United States at 20%, but the actual prevalence is difficult to identify due to minimally symptomatic disease and patients' ability to manage symptoms through self-treatment.

Significance of the Clinical Problem

The American Association of Nurse Practitioners (AANP) defines the overarching goal of the primary care practitioner as one that provides patient-centered care, promotes health, and prevents disease in partnership with patients and other healthcare services (AANP, 2019). However, barriers prevent the provider from developing a comprehensive picture of each patient's health status.

Medication reconciliation in the primary care setting is a quality and safety metric set by both the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC).

Lack of comprehensive, accurate records of prescription and non-prescription medications, herbal remedies, and nutritional supplements is a barrier to preventing patient harm and improving the quality of care (Serper et al., 2013). While the integration of data between electronic health records (EHR) and retail pharmacy systems has improved the reconciliation of prescription medications, there is no such system to alert them to the use of non-prescription medicines and other OTC products (Serper et al., 2013).

Inconsistent use of patient-specific screening protocols to identify at-risk groups requiring additional monitoring or treatment is a challenge to providing quality care (Zabaleta-del-Olmo et al., 2015). The primary care practitioner focuses on health promotion and the generalized care and prevention of common medical conditions, many of which have current evidence-based guidelines in place. Primary care practitioners may not have time to incorporate further risk assessment and screening tools during a routine office visit (Ireland, Laws, Gordon, Thompson, & Esterman, 2018). Additional barriers include increased provider workload and lack of knowledge or skills (Zabaleta-del-Olmo et al., 2015). Risk assessment for BE is also challenging due to disagreement among gastroenterology societies, inconsistent predictive models (Rubenstein & Thrift, 2015), and a lack of established U.S. Preventative Services Task Force (USPSTF) guidelines. These factors may prevent the primary care provider from delivering comprehensive care to their at-risk patients, reducing the safety and quality of care.

Question Guiding Inquiry (PICO)

An urban family practice clinic in north-central North Carolina has not instituted a standard of practice for completing medication reconciliation of non-prescription medication use for their patients at each visit. The clinic has an interest in determining the type and frequency of non-prescribed medications used regularly among their patient population. Because GERD has

an estimated prevalence of 20% of the U.S. population (Kellerman & Kintanar, 2017), the clinic can expect one in five of their patients to have either a diagnosis of GERD or to experience reflux symptoms, with some self-treating with OTC medications. Recognizing the patients taking OTC medications for reflux symptoms will improve GERD diagnoses. Improved recognition of OTC medication use for GERD will prompt treatment optimization and BE risk assessment, which encourages the initiation of early screening.

Population. Quality improvement interventions are directed at the medical providers and office staff in a primary care medical office.

Intervention. All medical office providers and staff will be included in the training on the OTC medication survey and GerdQ (Jones et al., 2009) tool. Providers will receive additional education on evidence-based guidelines related to the assessment and treatment of GERD, evaluation of the GerdQ tool results, and use of a BE risk factor assessment tool. The clinic staff will use these tools to evaluate OTC medication use, GERD symptoms, and BE risk in adult primary care patients age 18 years and older.

Comparison. Evaluation of the listed medication in the EHR, including OTC medications, will be conducted before and after each clinic visit for each patient completing the OTC medication tool. Data collected during the project will evaluate the number and percentage of patients taking OTC medications that were previously unknown compared to those with an accurate and inclusive medication record already documented in the EHR. Additionally, findings will identify new diagnoses of GERD and undertreated GERD as a percentage of all adult patients seen as new patients or for annual physicals during the implementation period.

Outcomes. Outcome data will denote adult patients taking OTC medications with type and frequency of use, those with new or undertreated GERD, the number at risk for BE, and

those with treatment changes based on the information obtained using the implemented tools. The goal of this project is to identify adult patients who self-treat with OTC medications to enhance comprehensive patient care, to identify those with new or undertreated GERD who are at increased risk for BE, and to ensure appropriate referrals for BE screening when indicated by elevated risk.

Summary

Common medical problems such as GERD may be missed when providers are unaware of patient self-treatment. Lack of knowledge of OTC medication, herbal remedy, and supplement use impacts the provision of comprehensive care. GERD, which can be easily self-treated with OTC medications, has the potential for significant morbidity and mortality because it is the primary risk factor in the development of BE, the precursor lesion for EAC. One method of mitigating these consequences is to identify all medications, including OTCs and supplements, being taken by patients so that providers can assist them in optimizing treatment and assess the risks for comorbid conditions.

This quality improvement project will introduce a patient-completed OTC medication survey in a primary care clinic where no standard practice to obtain this information exists. Patients with a diagnosis of GERD and those self-treating their reflux symptoms will complete the GerdQ to assess for the presence and severity of the disease. Using these tools is a step towards the delivery of a more comprehensive, patient-centered approach to care.

Chapter Two: Review of the Literature

A literature review (see Appendix A) was conducted to obtain background information and support the development of a quality improvement project to improve the identification of gastroesophageal reflux disease (GERD) and Barrett's esophagus (BE) risk in primary care. A search for information on disease epidemiology, diagnosis, current evaluation, and treatment of GERD and BE was completed. This review focuses on evaluation and treatment methods in primary care practice. Validated tools were identified during this search to help diagnose and evaluate treatment effectiveness for GERD.

Self-treatment of reflux symptoms is common in the United States (U.S.) due to the ready availability of over-the-counter (OTC) acid-reducing medications. Practitioners may be unaware of OTC medication use and, thus, not know of their patients' difficulty with reflux. An additional literature review determined the relative incidence of medication use underreporting and methods to improve patient reporting, i.e., through medication reconciliation.

Literature Appraisal Methodology

Sampling strategies. The electronic databases PubMed and One Search were used to identify the academic literature for this project. Individual and grouped search terms were used to identify pertinent literature from the following list: "gastroesophageal reflux disease," "GERD," "Barrett's esophagus," "epidemiology," "questionnaire," "GerdQ," "Reflux disease questionnaire," "RDQ," "over-the-counter medication," "non-prescription drugs," "self-treatment," "self-medication," "provider awareness," "medication safety," "medication documentation," "medication reconciliation," "process implementation," "GERD questionnaire," "primary health care," "ambulatory care," and "patient non-disclosure."

A literature search of peer-reviewed and scholarly work published within the last five years conducted using the search terms above resulted in more than 4,500 articles. Of 4,500 abstracts reviewed, 171 were selected for an in-depth assessment. Other pertinent literature was identified by reviewing reference lists of articles found during the initial search adding 16 additional items. Current clinical practice guidelines for GERD and BE were obtained directly from the American College of Gastroenterology (ACG) and the American Gastroenterological Association (AGA). Data on OTC medication use in the U.S. was obtained from the Consumer Healthcare Products Association (CHPA) website.

Evaluation criteria. Evidence for this project encompasses multiple disciplines, including nursing, medicine, and pharmacy. Evidence was ranked using Melnyk's level of evidence pyramid (Melnyk, 2011). Several systematic and scoping reviews were identified during the literature review. No pertinent meta-analyses nor authoritative opinions were found.

The key search terms of "medication reconciliation," "ambulatory care," "over-the-counter medications," "self-care," and "patient non-disclosure" were grouped during the literature search. These terms comprise the primary focus of this quality improvement project. Due to the volume of literature on these topics, articles were excluded if they did not relate directly to two or more of these key terms. North America or European studies were selected over studies from other continents due to similarities in demographics and health care. Preference was shown for evidence derived from studies conducted in the U.S.

Literature Review Findings

Impact of GERD in primary care. In the United States, GERD prevalence is estimated at between 6% to 30%, possibly due to population diversity and heterogeneity of the study tools to identify GERD symptoms (Richter & Rubenstein, 2018). GERD prevalence has increased by

approximately 50% since the mid-1990s (Kuipers & Spaander, 2018). Kellerman and Kintanar (2017) determined a sample weighted mean for GERD in the U.S. at 20%. The actual prevalence is difficult to identify due to minimally symptomatic disease and patients' ability to manage symptoms through self-treatment (Kellerman and Kintanar, 2017). GERD is the primary risk factor for BE with the most significant risk found among those with more frequent symptoms and longer durations (Runge et al., 2015).

Due to the prevalence and chronicity of gastrointestinal (GI) disorders, primary care providers are often the first clinicians to care for these patients. Practitioners must know the evidence-based guidelines for the management of common GI conditions to improve quality of life and reduce morbidity and mortality (Gikas and Triantafillidis, 2014). GERD is the fourth most common condition treated in primary care (Gikas and Triantafillidis, 2014). In 2009 GERD was associated with more than 9 million office visits (Richter & Rubenstein, 2018) and a cost of nearly $15.7 billion for prescription acid-suppressing medicines (Peery et al., 2019). GERD symptom management is a top ten GI reason for ambulatory visits annually and is the second most common GI diagnosis documented in ambulatory settings in the U.S. (Peery et al., 2019). The impact of GERD includes disease management costs, and economic and quality of life losses related to poor sleep, decreased productivity, and missed work (Kellerman & Kintanar, 2017).

GERD diagnosis in primary care. A clinical diagnosis of GERD is based on the presence of the typical symptoms of heartburn and regurgitation (sensitivity 30-76%; specificity 62-96%; Kellerman & Kintanar, 2017). The presence of atypical symptoms such as chronic cough, asthma, laryngitis, or dental erosions may also be diagnostic (Kellerman & Kintanar, 2017). A presumptive diagnosis may be confirmed through empiric treatment and response to

proton pump inhibitor (PPI) therapy (sensitivity 78%; specificity 54%; Kellerman & Kintanar, 2017). A GERD screening questionnaire combined with PPI treatment also correlates the diagnosis. Although a diagnosis of GERD can only be presumptive when made in the primary care setting, it is a cost-effective and non-invasive way to initiate prompt treatment (Kellerman & Kintanar, 2017).

Despite the prevalence of GERD among the general population, patients may not discuss symptoms with their healthcare provider. Once a patient is identified as having reflux symptoms, the provider must determine the best management strategy. Bolier, Kessing, Smout, and Bredenoord (2015) identified 65 tools for assessment of GERD symptoms, diagnosis, treatment response, and impact on patient quality of life. Because of variability among the tools, no single tool applied to all situations. This review provided a guideline for selecting an instrument that best meets clinician needs (Bolier et al., 2015). Of the seven tools appropriate for diagnostic assessment, only two were useful for this QI project. The GerdQ, translated into five languages, is a validated six-item patient-completed questionnaire (Bolier et al., 2015). The Reflux Disease Questionnaire (RDQ) is a validated, 12-item, patient-completed questionnaire that has been translated into nine languages (Bolier et al., 2015).

Jones et al. (2009) discussed the development and validation of a patient-centered tool for symptom evaluation and assessment of disease impact, the GerdQ questionnaire. The GerdQ is a patient-completed six-question tool with a sensitivity of 65% and specificity of 71% (Jones et al., 2009). Since its initial construction, the GerdQ has been validated in numerous languages and settings (Bolier et al., 2015). Grusell, Mjörnheim, Finizia, Ruth, and Berquist (2018) evaluated the validity of the GerdQ for assessing atypical presentations of GERD. For patients with cough, dysphagia, and globus sensation as the main presenting symptoms, sensitivity ranged from 23-

45%, while specificity ranged from 73-89%, suggesting that the GerdQ may effectively rule out reflux as a cause for atypical symptoms (Grusell et al., 2018).

The Reflux Disease Questionnaire (RDQ), developed as a diagnostic tool for GERD, is a 12-item questionnaire assessing six symptoms on a 6-point Likert scale (Bolier et al., 2015). Rey et al. (2014) found that the RDQ was useful in primary care to identify GERD based upon the patient's perception of whether their reflux symptoms were troublesome. When using a cut-off score of three, the RDQ tool sensitivity was 63.2%, and specificity was 80.2% for identifying GERD-related troublesome symptoms (Rey et al., 2014). This tool is also useful in assessing treatment response to PPIs, with a sensitivity of 65.4% and specificity of 71.8% (Rey et al., 2014).

BE risk assessment in primary care. Globally, GERD and BE incidence has risen over the last four decades (Runge et al., 2015) with a corresponding seven-fold increase in EAC (Hang et al., 2018). Prevalence of BE, determined through autopsy and population-based studies, ranges from 0.5% to 2% of the general population and from 5% to 15% in those with chronic reflux symptoms (Runge et al., 2015).

BE risk factors are chronic GERD, male sex, Caucasian race, age 50 years or older, central obesity, smoking, and family history of BE or esophageal cancer (Runge et al., 2015). One study found that a history of weekly GERD symptoms before age 30 was associated with a 15-fold increased risk of BE (Kuipers & Spaander, 2018). Crews et al. (2016) identified male gender (OR 3.8; 95% CI 1.7, 8.4) and central obesity (OR 3.0; 95% CI 1.2, 7.7) as additional independent risk factors for BE. They found that the probability of having erosive esophagitis or BE is 3.7 times higher for patients with three to four risk factors, and 5.7 times higher for patients with five or more (Crews et al., 2016). Tobacco use was found to have an odds ratio

(OR) of 2.0 (95% CI, 1.6, 2.3), and central obesity had an OR of 2.0 (95% CI, 1.5, 2.6) (Runge et al., 2015).

At present, there are no validated screening tools to help primary care providers identify patients at high risk for BE. The ACG recommends screening men with GERD who have had weekly symptoms for over five years when they have two additional risk factors (Shaheen et al., 2015). Because the risk of BE is much lower in women, Shaheen et al. (2015) suggest endoscopic screening on an individual basis and only when multiple risk factors exist.

OTC medication use. Information obtained from the Consumer Healthcare Products Association (2019) notes that 81% of U.S. adults choose OTC medications as their first line of treatment for minor symptoms, providing relief to approximately 60 million people who would not otherwise seek care. In 2017 more than $34 billion were spent on OTC products, which includes $2.6 billion spent on nonprescription heartburn remedies (CHPA, 2019). Many factors, including health literacy, access to care, and economics, influence OTC medication choice among all adults (Noone & Blanchette, 2018). Self-care is an essential aspect of consumer health as it empowers patients to autonomously manage common conditions, increase productivity, reduce healthcare expenses, and is necessary for preventative health (Noone & Blanchette, 2018). Although the ready availability of OTC products allows symptomatic self-treatment of minor illnesses and chronic conditions, healthcare providers are often uninformed about their patients' symptoms and OTC medication use (Noone & Blanchette, 2018). This lack of knowledge by providers may lead to increased risk of adverse drug events (ADE), which are two to seven times more likely to occur in older adults (Albert et al., 2014) and lead to 178,000 hospitalizations annually. Several studies estimate that between 35% and 47% of older adults use OTC medications regularly (Albert et al., 2014).

OTC medication reconciliation in ambulatory care. Medication reconciliation in the primary care setting is a quality and safety metric set by both the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission (TJC). Lack of comprehensive, accurate records of prescription and non-prescription medications, herbal remedies, and nutritional supplements is a barrier to preventing patient harm and improving the quality of care (Serper et al., 2013). While the integration of data between electronic health records and retail pharmacy systems has improved the reconciliation of prescription medications, there is no such system to alert them to non-prescription medicines and other OTC product use (Serper et al., 2013).

Data about patient disclosure of their health status and medication use is limited. Levy et al. (2018) sought to identify the prevalence of intentional nondisclosure of seven types of relevant medical information through two surveys, designated as the MTurk and SSI, finding that nondisclosure occurred 81.1% (MTurk) and 61.4% (SSI) of the time. Data obtained from the same two surveys identified that deliberate nondisclosure of medication occurred 15.5% (MTurk) and 10.4% (SSI) of the time (Levy et al., 2018). Some reasons for nondisclosure included fear of judgment (81.1% and 64.1%), embarrassment (60.9% and 49.9%), not wanting to take up the providers time (45.2% and 35.9%), not thinking that it mattered (38.6% and 32.9%), and feeling that the provider could not help the problem (27.7% and 28.9%; Levy et al., 2018). While some nondisclosure may be intentional, Serper et al. (2013) found that there was incongruence in what patients believe their providers know about the medications they take. This study found that more than 90% of patients thought their provider knew about all their prescription and nonprescription medicines, but told the provider about their OTC medication use only 46% of the time (Serper et al., 2013).

Medication errors, ADEs, and polypharmacy are significant consequences of medication list inaccuracies (Holt & Thompson, 2018). Medication reconciliation is one way to mitigate these consequences and improve patient safety, but this has been a challenge in ambulatory settings due to its time-consuming nature (Holt & Thompson, 2018). TJC identifies medication reconciliation as a national patient safety goal across all healthcare settings and, in ambulatory care, accepts the showing of a good faith effort as evidence of meeting this goal (Holt & Thompson, 2018).

Numerous interventions have been trialed to improve medication reconciliation in ambulatory settings, but there are significant barriers, including time constraints and lack of patient participation (Holt & Thompson, 2018). The best method uses a multipronged, multidisciplinary approach involving medical providers, pharmacists, nurses, medical office staff, and patients (Holt & Thompson, 2018). A scoping review of medication reconciliation interventions identified common themes for obtaining information, including patient and caregiver interviews, medication lists, medications brought to the clinic, discharge summaries, and pharmacy generated lists (McCarthy et al., 2016). The majority of medication reconciliation interventions involve interviewing, reviewing medication lists, or bringing medications to clinic visits (McCarthy et al. 2016). Brown-bagging, the process of bringing all medicines, including OTCs and supplements to the office visit, is a common practice for reconciliation. Multiple studies of brown-bagging show that many patients do not bring all of their medications, and the process of looking at individual medicine vials and boxes is time-consuming (Sarzynski, Luz, Rios-Bedoya, & Zhou, 2014). Sarzynski et al. (2014) found that medication reconciliation was improved with structured interviewing, regardless of whether medications were present or not. One randomized control trial of two interventions, providing patients with a printed copy of their

medication list for review and using open-ended questions, found that medication list agreement increased to 75.6%, but only when both interventions were used (Wolff, Nowacki, Yeh, & Hickner, 2014). Common among all of the studies in this literature review was the theme of inconsistent reconciliation of OTC medications. A study aimed at improving OTC medication reconciliation used a human body diagram and symptom list to prompt patients to provide a two-week recall of nonprescribed medicines taken (Jarrett, Cochran, Baus, & Delmar, 2019). Jarrett et al. (2019) identified improvement in documentation of OTC medications in 82%, PRN medications in 3%, and herbal supplements and vitamins in 28% of the records following the intervention. Patient prompting and open-ended questions showed the most promise for improving the reconciliation of OTC medications.

Facilitators of medication reconciliation include engaging patients in the process and instructing them on its importance, engaging clinic staff and providing education and feedback, collaborating with outside providers, integrating the process into the current workflow, and low cost (McCarthy et al., 2016). Another qualitative study looking at barriers and facilitators of medication reconciliation in primary care found that nearly all patients perceived the value obtained through the process (Uhl, Muth, Gerlach, Schoch, & Müller, 2018). Patient barriers revolved around reluctance to provide information due to a sense of lost autonomy, not wanting to disclose sensitive diagnoses, lack of awareness of the potential harm nonprescribed medications can cause, and fear of having to justify their medicine use (Uhl et al., 2018). The most prevalent provider barrier found among reviewed studies on medication reconciliation in ambulatory care was time poverty.

Limitations of the Literature Review Process

Limitations and gaps in the current literature were discovered through the review and synthesis process. Medication reconciliation processes often focused on times of transition between care settings rather than at every appointment. There was limited evidence on ways to elicit information on over-the-counter medications and supplements, an area of concern in almost every study. Additionally, medication reconciliation most often relied on the use of electronic health records, which may not provide the appropriate tools for implementation of a thorough process in a small primary clinic. Few tools were identified to aid specifically in the OTC medication reconciliation process.

Discussion

Conclusion of findings. This quality improvement project was developed to identify patients at high risk for BE, with a long-term goal of preventing esophageal adenocarcinoma. Because GERD is the primary risk factor in the development of BE, identifying patients with GERD or who are self-treating reflux symptoms is essential. GERD is a widespread disease that impacts one in every five people, making it likely that the primary care provider will see four to five patients per day with this condition. Because GERD is easily treatable with OTC medications, patients may not discuss their reflux symptoms with their provider. The common problem of lack of disclosure regarding OTC drugs and inconsistencies remaining in the EHR after medication review was evident in several studies that evaluated medication reconciliation. When inconsistencies were discovered during review processes following medication reconciliation, omissions universally involved OTC drugs.

Due to GERD and reflux symptom responsiveness to self-treatment, OTC medications are frequently used for symptom management. Patients who take OTC medications to treat reflux

symptoms are less likely to notify their primary care provider when there is no routine process to evaluate the type or frequency of OTC medication use. Identification of GERD is essential in gauging Barrett's esophagus risk. An OTC medication survey and provider review of frequent OTC medicine use will identify patients who should be assessed more thoroughly for GERD. The validated tool, GerdQ, is a short, patient-completed form that aids in the diagnosis of GERD in primary care. Provider identification of a GERD diagnosis provides the opportunity for education on lifestyle modifications, optimization of treatment, and assessment of additional risk factors for BE. In the short term, better management of GERD will improve patients' quality of life.

Advantages and disadvantages of findings. The primary benefit of the proposed project is the enhancement in comprehensive, patient-centered, and holistic care through improved provider knowledge of all medications and troublesome symptoms the patient may be experiencing. The format of the intervention should prompt increased communication about health issues experienced by patients, leading to better management. Reducing symptom burden, drug interactions, and the potential for adverse drug events, are other important outcomes to be considered.

The primary disadvantage of implementing this project is the potential for an increased workload due to new forms and additional documentation. Time spent on paperwork diminishes time caring for patients and reduces clinic productivity. Buy-in from all staff may be difficult if other providers don't recognize a gap in care or are not involved in tool or process development.

Utilization of findings in practice change. The literature review identified a gap in practice related to provider-patient communication and knowledge of patients' medication use, particularly OTC medications. Patients may not discuss self-treated problems with their primary

care provider, and the provider may not routinely ask about self-care. OTC medications are often overlooked during routine medication reconciliation, and patients may not feel that it is essential to include non-prescribed drugs. Studies reviewed identified several ways to help reduce omissions during medication reconciliation, including patient prompts and interviews regarding their medicines. A tool that prompts patients to consider and document their OTC medication usage may help to close the gap. When this tool is followed by medical provider review and open-ended discussion, a complete medication list can be generated. Although not well studied in primary care, accurate and complete medication records in the hospital setting are shown to reduce the risk of medication duplication, drug-drug interactions, and adverse events.

The second piece to this project is identifying patients at increased risk for Barrett's esophagus. An accurate medication record provides the primary care provider with knowledge about their patient's health concerns. Any patient who is taking medications regularly to treat GERD or reflux symptoms will complete the GerdQ, a validated diagnostic tool to assess the likelihood and severity of GERD. With this knowledge, the provider will consider the patient's additional risk factors for Barrett's esophagus and, if evaluation identifies high risk, will manage according to ACG recommendations.

Barriers to implementing new programs in ambulatory care are identified in the literature. The most problematic barrier to implementation of this project at a primary care clinic is time poverty. Patients are scheduled every 20 minutes, and there is not a nurse or certified medical assistant (CMA) to room patients or complete pre-visit screening tools. Providers often room their patients and perform other duties such as lab draws. The additional time it takes to review another document and record additional medications may take time away from direct patient assessment and evaluation.

The most essential facilitator is the recognition that a lack of knowledge about OTC medication use in their patients is problematic. Buy-in and involvement in process development are essential factors to consider. Early and ongoing discussions regarding the project and processes, along with provider and staff education prior to implementation, will facilitate a smooth implementation process.

Summary

A patient-completed OTC medication survey will be introduced in a primary care clinic to improve the accuracy and completeness of the patients' medication records. Patients who are taking prescribed or OTC acid reflux or heartburn medications will complete the GerdQ to establish a diagnosis of GERD and determine the severity of the symptoms. New OTC medications discovered with the OTC medication survey may encourage communication between the provider and patient about their health and troublesome symptoms, leading to comprehensive, patient-centered care. A diagnosis of GERD should prompt additional review by the medical provider to assess for other risk factors of Barrett's esophagus, which may indicate that screening is needed.

This quality improvement project meets the Institute for Healthcare Improvement (IHI, 2020) Triple Aim objectives of improved per-capita costs, the experience of care, and population health. As identified by CMS and TJC, medication reconciliation is an important measure that enhances the quality and safety of patient care. Patients believe that provider knowledge about their medications is significant to the receipt of good care as well. Complete and accurate medication records can reduce drug-drug interactions and adverse drug events preventing emergency department visits and hospitalizations. Patient-completed surveys and assessment tools such as the OTC medication survey tool and GerdQ allow the medical provider to gather

essential data without reducing their time with the patient. These tools may also improve communication with patients by prompting discussion about changes in their health. Adequate treatment of GERD is shown to improve patient quality of life by increasing productivity and reducing time away from work. Additionally, knowledge of a GERD diagnosis will provide the opportunity for providers to assess for high risk of BE, allowing patients to be screened early. Early screening increases the potential to prevent EAC, thereby reducing the associated financial burden and impact on quality of life that accompanies a cancer diagnosis.

Chapter Three: Theory and Concept Model for Evidence-based Practice

This chapter examines the theory and concepts that ground evidence-based practice change. Once a problem has been identified, the clinician must identify the general ideas or concepts related to the problem. Analysis and mapping the interactions among the pertinent concepts permit the project team to visualize concept associations and their influences on one another. Theory provides a framework for project development and implementation and guides the project along a prescribed path. This project will use the Iowa Model of Evidence-based Practice. Lewin's Change Theory will be incorporated in the Iowa Model framework to enhance implementation, adoption, and sustainability.

Concept Analysis

Defining the ideas presented in this quality improvement project provide the background for understanding the underlying concepts and their connections to each other (See Appendix B). These interwoven concepts impact the project and guide the interventions and goals.

Patient self-care. The concept of self-care concerns how a person understands and addresses their personal needs to optimize health. The mechanisms of self-care include activities to improve physical, psychological, spiritual, and social well-being. In the project's context, self-care relates to the use of over-the-counter (OTC) medications and supplements to prevent illness, improve health, or treat symptoms.

Patient nondisclosure. Nondisclosure of information to a healthcare provider can be an intentional or unintentional omission. Patients may not realize that self-care activities may interfere with prescribed care. Patients may be embarrassed or fear judgment from their provider about their self-care choices. Lack of disclosure influences the provider's ability to have a comprehensive view of patient health.

Patient-provider communication. Communication between patients and healthcare providers is multimodal through oral, written, and electronic communication, non-verbal cues, visual prompts, and patient-completed tools. Using several communication methods during patient encounters helps overcome barriers, prompts discussion, and improves holistic care. Providers who display open and non-judgemental behaviors influence patient trust leading to enhanced communication.

This project uses an OTC medication survey to mitigate one patient-provider communication gap. The tool is designed to prompt patient recall of OTC medication use. Discussion of the survey contents during the patient encounter enhances the provider's understanding of patient self-care actions and health-related goals.

Medication reconciliation. Medication reconciliation is the process of identifying and documenting all prescribed and OTC medications, herbal remedies, and supplements in the patient health record. It is essential for provider understanding of patient self-care and health status and should be completed during every patient encounter. Reconciliation methods vary among different practices and care settings. When a medication reconciliation process is used consistently, medication records are more accurate. Primary care providers are coordinators of patients' overall care and are essential in preventing drug interactions and adverse events.

Disease risk assessment. Risk assessment in healthcare is a crucial practice that influences health and outcome goals. Risk assessment involves evaluating the factors that impact health negatively. Risk is best assessed when the provider is fully aware of all the factors that influence the patient's health and well-being. Assessing modifiable and non-modifiable risk factors leads to the development of a care plan that mitigates risk, prevents disease, and promotes health. Patient-determined goals should guide risk assessment, disease screening, and treatment.

Absent or incomplete risk assessment leads to missed screening and preventive treatment opportunities. Alternatively, it may lead to unnecessary screening, needless testing, and increased healthcare costs. In disease processes with low population prevalence, such as Barrett's esophagus (BE), risk assessment is necessary to determine which patients should be screened.

Theoretical Framework

A theoretical framework helps to study a problem of interest and evaluates its interrelated concepts. This framework guides the development, implementation, and evaluation of a Doctor of Nursing Practice (DNP) scholarly project. Through a synthesis of the literature, current evidence can be used to solve problems and guide practice change.

Iowa Model of Evidence-Based Practice. Incorporating best practices in healthcare is challenging due to a changing healthcare environment, the discovery of new knowledge, and provider time demands. The Iowa Model of Evidence-Based Practice, based on Roger's Diffusion of Innovations, delivers a framework to guide practitioners from defining a problem of interest to translating evidence into practice (see Appendix C; Iowa Model Collaborative [IMC], 2017). The IMC (2017) provides tools for each step to aid project development. The Iowa Model identifies decision points to streamline the process of improving care quality. These steps align with the framework that guides the DNP scholarly project.

The first step of any evidence-based project is discovering areas requiring change, and then defining the problem. The Iowa Model uses a PICO (Population, Intervention, Comparison, Outcomes) statement as a guide (IMC, 2017). After adequately defining the problem, the first decision point is reached: Is this problem a patient, organization, or system priority? If so, a multidisciplinary team should be formed, followed by the development of an action plan and timeline (IMC, 2017).

Step two is a review and synthesis of the literature to locate and evaluate current evidence that supports the desired change (IMC, 2017). After the literature is evaluated, the second decision point is reached: Is there enough available evidence to support the change? If there is inadequate evidence to inform the change, several options exist: conduct research to fill the gap or expand on or develop additional topics to address the need (IMC, 2017).

Once sufficient support is identified, the team can proceed to step 3: project development and testing the practice change. The revised Iowa Model recommends changes that are patient-focused rather than organization-focused (IMC, 2017). Additionally, identifying resources and implementation strategies should be addressed (IMC, 2017). Appropriate implementation strategies encourage stakeholder support through increased awareness and interest, building a knowledge base, and improved commitment (Cullen & Sigma Theta Tau International, 2017). The implementation phase may pass through several iterations if outcomes from pilot testing are not as anticipated. Decision point three occurs following implementation: Is the change appropriate for adoption (IMC, 2017)? If the answer is no, then reevaluation and redesign should occur. If the practice change is affirmed, the project team should proceed to the final steps of integrating and sustaining the practice change, and disseminating the findings (IMC, 2017).

White and Spruce (2015) used the Iowa Model to implement an evidence-based guideline for handwashing to reduce the incidence of surgical site infections in a perioperative setting. The project team discovered that using multiple implementation strategies led to greater acceptance and support for practice change (White & Spruce, 2015). This suggests that a project has a higher chance of success and sustainability when several appropriate implementation strategies are used.

Application of the Iowa Model to practice change.

Step one: Defining the problem. In the U.S., gastroesophageal reflux disease (GERD), BE, and esophageal adenocarcinoma (EAC) are increasing in prevalence and often remain undiagnosed until the late stage. One in five patients seen in primary care will have GERD, but patients often self-treat symptoms without informing their provider. Anecdotal evidence and the literature informed us that patients do not routinely discuss OTC medication use or self-treated problems unless prompted or when there was a medication reconciliation system in place.

Decision point 1: Is this problem a priority? Implementing a medication reconciliation process was a priority. A provider's ability to provide comprehensive, patient-centered care relies on having complete knowledge of patients' problems, health goals, prescribed treatments, and self-care. Some self-care measures, such as OTC medication use, can interfere with prescribed treatments through interactions or adverse events. Lack of provider knowledge regarding self-treated problems impedes treatment optimization and screening interventions, which influence long-term outcomes.

Step 2: Literature review and synthesis. The literature confirmed the extent of the identified issues and offered evidence that patient non-disclosure warrants intervention. Medication reconciliation was shown to improve disclosure of OTC medication use. Patients with self-treated GERD symptoms would be identified, assessed for symptom severity, and screened for BE risk.

Decision point 2: Is there enough evidence to support the change? The evidence found was sufficient to support a change in practice. A tool prompting patients on their OTC medication use was developed for use in a primary care clinic where no process existed. Patients taking reflux medications used the GerdQ questionnaire to evaluate the severity and impact of

their symptoms. The medical provider optimized reflux treatment and determined the patient's risk of BE based on the presence of other risk factors following the American College of Gastroenterology (ACG) recommendations.

Step 3: Implemention of practice change. The clinic staff and providers worked with the project lead to design tools and processes. Teamwork improved buy-in from those involved in the process. Educational sessions were conducted with the staff before implementation. The process was patient-centered and multidisciplinary using tools designed to prompt patient disclosure of self-treatment measures and a validated tool to evaluate and diagnose GERD. Using PDSA (Plan, Do, Study, Act) cycles, reevaluation of the process occurred every two to three weeks with revision of the process occurring as the stakeholders identified problems.

Decision point 3: Is the change appropriate for adoption? Following the implementation processes, frequent evaluations, and assessment of project data led to project and process modification to meet clinic objectives. Frequent revaluation of the data showing early positive outcomes reinforced buy-in to the process and justified the need to adopt the change into practice.

Step 4: Integrate and sustain practice change. By continuing to work with clinic staff to assess and modify the process, full integration into the practice setting would be achieved. Modifications focused on how to best meet the need of the patients, staff, and clinicians. The final step to fully integrate the practice change would be the inclusion of the tools within the electronic health record (EHR). Patients with access to the patient portal would be able to use the tools before attending their appointment. Integration with the EHR would reduce staff and provider time burden and improve clinic flow.

Step 5: Disseminate the findings. Project findings were disseminated through a final report and presentation to the clinic staff, and by virtual podium presentation at the East Carolina University College of Nursing. Upon completion, the DNP scholarly project paper will be uploaded to the ScholarShip, East Carolina University's institutional repository of scholarly works.

Evidence-Based Practice Change Theory.

Lewin's Change Theory. Change in healthcare is inevitable. Discovery of new evidence to guide practice, shifting practice environments, and changes in patient, provider, and organizational expectations cause demand for change that promotes improvement in the quality of care. Implementing change among these competing interests is challenging and best managed when guided by theory.

Lewin's Change Theory (see Appendix D) is a three-step framework for influencing the contextual factors that facilitate or impede change (Manchester et al., 2014). Step one, unfreezing, involves determining the need for change, identifying the stakeholders involved, and recognizing the barriers and facilitators to changing practice (Manchester et al., 2014). To facilitate the unfreezing process, the driving forces for change must overcome the resistant forces to upset the status quo (Manchester et al., 2014). Once unfreezing occurs, movement, the second step, can begin. Movement is the implementation process involving cycles of evaluation, reassessment, and refinement, which occur until the anticipated outcomes are achieved, and the process or behavior becomes routine (Manchester et al., 2014). Once the policy, practice, or behavior is widespread and becomes an accepted part of the practice, refreezing can begin. Refreezing, the third step of Lewin's Change Theory, involves using reinforcement measures that lead to the adoption and sustainability of the practice change (Manchester et al., 2014).

Application to practice change. Lewin's change theory directly aligns with steps three and four of the Iowa Model for Evidence-based Practice Change because it enhances the framework for implementation, adoption, and sustainability.

Unfreezing. The clinical problem identified at the project site is a lack of complete medication reconciliation at each visit. Incomplete medication reconciliation impacted the providers' ability to provide comprehensive patient care. Providers' lack of knowledge regarding patient self-treatment placed patients at risk for adverse drug effects, drug interactions, and missed diagnoses. The stakeholders were the clinic staff, providers, and patients. Driving forces were the providers' desire to provide comprehensive care, cost-effective program to implement, and having a project lead from outside of the clinic workforce. Restraining forces included a negative impact on time management and clinic flow and increased work caused by the necessity for manual input into the EHR. Including staff and providers in tool development and implementation process, and providing education on the problem background, expected outcomes, and implications to their practice assisted in overcoming the status quo. Piloting a limited OTC questionnaire to judge workflow and time demands eased concerns. Providers completed a survey after each applicable patient visit. The post-visit survey indicated when new problems, medications, a new diagnosis of GERD, or high risk for BE was identified, and identified treatment plan changes.

Movement. Step two began with project implementation. A pilot OTC questionnaire limited to medications taken for gastrointestinal (GI) complaints permitted evaluation of the workflow. As staff members became accustomed to the reconciliation process, additional OTC medication groups, such as pain medicines, cold and sinus medicines, or topical products, were

added to the questionnaire. Once every two to three weeks, staff and providers discussed how the process worked with the team lead, and adjustments were made as needed.

Refreezing. As the project neared completion, measures to reinforce the change were implemented. These included posters reminding patients to discuss their OTC medications with providers and EHR prompts reminding providers to ask about OTC medication use. Dissemination of project findings of positive outcomes reinforced the change, leading to adoption. Integration of prompts into the EHR and using the electronic patient portal to send OTC medication surveys before appointments should ensure project sustainability.

Summary.

The ability to translate evidence and facilitate evidence-based practice change is the hallmark of the DNP-prepared nurse. Identification of practice and organization problems and their related concepts, and looking at issues from multiple perspectives are valuable skills when developing a practice change project. Visualization of concept relationships through concept mapping further defines the problem and suggests potential solutions. Evidence-based practice change is a complex, multidimensional process that is best guided using a framework based on sound theory.

This project uses both the Iowa Model for Evidence-based Practice Change and Lewin's Change Theory. Using a step-wise process, the Iowa Model guides the project, beginning with the development of a problem statement, through conducting a literature review, to implementation, and ending with the integration of the practice change and disseminating the findings. When used in conjunction with Lewin's Change Theory's unfreezing, movement, and refreezing processes, implementation and integration will achieve greater success.

Chapter Four: Pre-implementation Plan

A successful quality improvement (QI) project begins with a detailed plan. This chapter discusses the pre-implementation process, which began with defining the purpose. Active communication among the project team members assessed their readiness for change. Project pre-implementation involved risk analysis, project budgeting, and development of project tools. The institutional review board (IRB) process is discussed, along with other methods used to ensure patient safety.

Project Purpose

The project's purpose was to identify (1) previously unreported over-the-counter (OTC) medication use, and (2) to quantify gastroesophageal reflux disease (GERD) symptoms. These variables determine which patients are at risk for developing Barrett's esophagus (BE). After the OTC medication survey and GerdQ are implemented, the primary care provider will determine which patients have unidentified or undertreated GERD. The identification of GERD prompts the assessment of additional BE risk factors and guides the plan of care.

Project Management

Organizational readiness for change. When considering healthcare delivery changes, the resulting changes, or outcomes, should be patient-centered. Discussion with the site champion identified several areas to improve comprehensive patient care at the project site. Anecdotal practice evidence suggested that patients often required prompting about OTC medication use, which often led to the discovery of additional health issues. Understanding of the lack of a standardized assessment of OTC medication use and the desire to provide patient-centered care drove the organization's readiness for change. The principle of patient-centered care is exemplified by the following: discovery of self-medication and underreported GERD

symptoms leads to the ability to assess BE risk, identify potential drug-drug interactions, and prevention of adverse drug events.

The Health Resources and Services Administration (HRSA, n.d.) identified three characteristics that define organizational readiness: leadership commitment to QI, clinician acknowledgment of the value of QI, and the ability to collaborate. The site champion expressed interest in the proposed project and garnered support from the clinic's medical director. Due to the small size of the project site, the entire staff worked with the project lead to foster change and improve quality, patient-centered care for their patients.

Interprofessional collaboration. The project team consisted of the DNP student project lead, the DNP faculty advisor, the family nurse practitioner (FNP) site champion, the physician medical director, a new-to-practice adult-gerontology nurse practitioner (AGNP) provider, a certified medical assistant (CMA), and the office manager. The project lead was responsible for QI project coordination and development through collaboration with the site champion and support of DNP project faculty. Additional project lead responsibilities included team education, data compilation, and providing project support throughout the QI project.

During implementation, the CMA provided the OTC medication survey and GerdQ tool to all new adult primary care patients and adult patients presenting for annual physicals at appointment check-in. All three providers reviewed the OTC medication survey for unreported medication use, scored and reviewed the GerdQ tool, evaluated BE risk factors, and addressed plan-of-care changes. The office manager provided support to the CMA and monitored for project-induced workflow issues. All forms were collected and secured in the site champion's office daily. In addition to project participation, the medical director monitored the impact on clinic productivity and workflow.

Risk management assessment. As a part of risk management, a SWOT analysis was conducted during pre-implementation to assess the strengths, weaknesses, opportunities, and threats related to this QI project. These variables had opposing positive and negative impacts on the project. By amplifying the strengths and opportunities, the weaknesses and threats were minimized.

Strengths. There were several strengths that supported this QI project. Voluminous data on the increase in GERD, BE, and EAC prevalence in the U.S. illustrated the depth of the problem. Medication reconciliation was a quality and safety metric across all care settings in the U.S. Working with a small practice site allowed for better communication and cooperation among team members. There was leadership support for quality improvement initiatives, and there were no front-end clinic costs to implement at this project site.

Weaknesses. Several weaknesses impacted this project. There were a lack of best practices and validated tools for OTC medication reconciliation. The OTC medication reconciliation and GerdQ tools were completed on paper, rather than integrated into the EHR. Manual medication reconciliation into the EHR caused increased staff workload. The project lead compiled data manually.

Opportunities. Involving all clinic staff in the QI process supported a sense of project ownership, which encouraged participation. By taking advantage of the site champion's enthusiasm, project buy-in was improved. The clinic's patient population matched the BE risk profile, which improved the odds of impacting patient's long-term health. Integrating the tools into the EHR and allowing patients to complete tools pre-visit would improve participation and reduce staff workload.

Threats. An early threat to project success was that initial discussions and project planning only included the site champion. This could have led to resistance to participation. Another project completion threat was the potential for lack of recognition by patients of the importance of including OTC medications during reconciliation. A financial threat was that back-end costs to integrate the project tools into the EHR might be prohibitive. Finally, some patients may not possess the technology or skills to access the tools if integrated into the EHR.

Organizational approval process. During the Fall, 2018 clinical practicum, the project lead encountered several instances of unknown OTC proton pump inhibitor (PPI) use by clinic patients. Additional investigation highlighted data collection inconsistencies on OTC medication use. Discussion of the increasing prevalence of GERD, BE, and EAC and measures to improve identification occurred with the site champion over several weeks, and possible methods to improve recognition were discussed. A mock-up tool for the evaluation of OTC medication use and the GerdQ tool were presented for evaluation. The site champion expressed concern that the full OTC medication survey would lead to a sudden increase in workload, negatively impacting workflow. This led to an agreement to implement this tool slowly, surveying OTC GI medications first, and then adding other OTC medication classifications after workflow impact was assessed. The medical director was presented with the project outline and agreed to allow the QI project to proceed. Final approval was received, and a letter of support (See Appendix E) was obtained from the FNP serving as site champion.

Information technology. The clinic EHR was used to determine general patient population demographics and the average number of adult primary care patients seen per week. Microsoft® Office and Excel were used to compile, analyze, and display data using tables, charts,

and graphs. Microsoft® PowerPoint was used to create an initial educational presentation for the project team and final project poster displaying the data and project outcomes.

Cost Analysis of Materials Needed for Project

The financial costs of implementing this QI project were minimal. They primarily consisted of administrative costs associated with printed educational materials, and the OTC medication survey, GerdQ, and post-visit provider survey. Additional costs included food provided during a Lunch-and-Learn education session. Travel expenses for ten round-trip visits to the clinic were included in the budget. See Appendix F for the proposed QI project budget. Non-monetary costs included time away from work and personal time used to complete the QI project.

Use of a personal LaserJet printer to print educational handouts, OTC medication and post-visit provider surveys, and GerdQ tool provided administrative cost savings. Additionally, all data was compiled and analyzed by the project lead, leading to no added personnel costs.

Plans for Institutional Review Board Approval

Permission to move forward with the IRB process was first received from the project faculty after reviewing the project plan and tools. The East Carolina University (ECU) IRB process involved completing a QI/program evaluation self-certification tool (See Appendix G) to assess the type of IRB process required. This initial IRB review determined the project to be quality improvement; therefore, the full IRB process was not needed. The project implementation site, a small single-office family practice, did not have an IRB process. They followed the policies set forth during the ECU review process.

Plan for Project Evaluation

Demographics. Data obtained using the DNP Project Data Collection Tool (See Appendix H) was compiled and presented as aggregate quantitative data representing new adult patients and patients presenting for annual physical appointments. This data identified the number of patients seen, number completing the OTC medication survey and GerdQ, new GERD diagnoses, and the number considered at risk for BE. The project lead reviewed each completed BE risk assessment to identify the number of male patients with GERD with two additional risk factors. No individually identifiable health information was collected. This data was reported using frequency counts and percentages, i.e., the total number of patients seen compared to a new diagnosis of GERD, or diagnosis of GERD compared to high risk of BE. This information was presented in table format.

Outcome measurement. Both process and outcome measures were identified during this QI project. Process measures monitored the number of OTC surveys and GerdQ tools completed, the number of GerdQ tools correctly scored, and the number of provider post-visit surveys completed. Process measures determined whether the project was fully implemented to include all applicable patients. Full implementation improves the odds that all at-risk patients would be identified. Outcome measures included identification of the number of new patients with GERD, patients at risk for BE, and disposition based on this information. Three disposition levels were identified: (1) monitor/continue current treatment, (2) modification of treatment plan through lifestyle modifications or medication changes, and (3) referral to GI. Outcome measures provided an indicator of the impact of the project on improved patient care.

Evaluation tool. The OTC medication survey was explicitly created for this project to identify the types and frequency of OTC medication usage among adult primary care patients

(See Appendix I). This tool used written prompts to aid patient recall of the types of OTC medications they used. Patients taking OTC medications to treat upper GI symptoms such as heartburn, acid reflux, or regurgitation completed the GerdQ, a validated six-item tool used to diagnose and quantify the severity and impact of GERD in the primary care setting. The GerdQ was initially evaluated with a sensitivity of 65% and specificity of 71% (Jones et al., 2009). Since its development, the GerdQ has been revalidated numerous times with similar results in English and several other language translations. Permission for use was obtained from the owner, AstraZeneca (See Appendix J), with copies of the tool provided in English and Spanish language translations (See Appendices K and L). The GerdQ scoring tool was also provided (See Appendix M).

Providers were given a five-item post-visit survey to summarize each patient visit (See Appendix H). The first four questions consisted of yes/no response items that asked if new patient information was discovered because of the OTC medication survey or GerdQ, if the information prompted a treatment change, and if high risk for BE was identified. A treatment change was defined as education, medication, testing, referral, or other treatment. The fifth item asked the provider to determine the patient disposition from five choices and to circle all options that applied.

Data analysis. Descriptive statistics, percentages, and measures of central tendency were used to present the quantitative data obtained during implementation. Compiled information from the collected surveys and GerdQ tool was entered into a Microsoft® Excel spreadsheet describing the data obtained during each PDSA cycle throughout the implementation period. All GerdQ tools were reviewed each week for correct scoring. When scoring errors were identified, the scoring instructions were reinforced with the site champion. Each of the tools discussed was

new to this practice. Thus, there were no practice benchmarks with which to compare. Additionally, there were no defined quantitative screening parameters for BE.

Data management. The surveys and GerdQ were collected and stored by the site champion at the end of each clinic day. The project lead reviewed and compiled the data at the project site every two to three weeks. Because no personally identifiable health information was collected, no special procedures were required to protect the data. All data were stored on a password-protected laptop computer and backed up on a password-protected desktop computer. A backup of the data occurred biweekly. The surveys and GerdQ tools remained at the project site and were shredded at the completion of the project. Aggregate project data was available for review with site team members and project faculty during the implementation period. Only the project lead had access to editable Microsoft® Excel files.

Summary

A great deal of planning occurred during pre-implementation. This was a complex, multistep process that ensured a successful QI project. The process began by defining the project's purpose: to identify patients at high risk for BE. Assessing readiness for change and project risk was essential. The ECU IRB identified this project as quality improvement, indicating there was minimal risk of harm. No personally identifiable information was obtained, and all data was presented in aggregate, ensuring patients' health information remained secure.

Developing the OTC medication survey, selecting the GerdQ, and defining methods for data compilation, analysis, and management required a great deal of thought and time. Planning during the pre-implementation phase ensured a well-developed project and provided a framework for successful implementation.

Chapter Five: Implementation Process

Successful implementation can only occur after thorough planning during the pre-implementation phase. The implementation process included the delivery of the assessment and data collection tools, quality improvement (QI) project team education, ongoing process assessment during the implementation period, and compilation of data. This chapter describes the implementation process and how the process was adapted to meet the needs of the project site.

Setting

The setting for this Doctor of Nursing Practice (DNP) project was a privately-owned single-office family practice clinic located in urban north-central North Carolina. This practice is unaffiliated with the local university medical centers but has access to each center's patient medical records via the Epic electronic health record (EHR). The primary care population served by this entity consists primarily of patients with private health insurance and Medicare, with less than 10% being self-pay. Greater than 80% of their patients are adults age 18 years or older. Caucasians comprise 70% of their patient population. The three providers at this practice see approximately ten adult primary care patients each per eight-hour day, with one to two new or annual physical patients seen per day. Roughly 20% of the patients seen at this clinic are being treated solely for opioid dependence and are not considered part of the primary care population.

It is estimated that 20% of the US population has gastroesophageal reflux disease (GERD; Kellerman and Kintanar, 2017). The demographic profile of an at-risk person for Barrett's esophagus (BE) is a Caucasian male over 50 years of age with central obesity and a current or past smoking history who has chronic GERD. The patient population at this clinic made it ideal for the implementation of this project to identify patients at high risk for BE. Additionally, a high percentage of patients at this project site are insured, which will allow at-

risk patients to afford plan-of-care changes for GERD treatment and to obtain screening examinations for BE if warranted.

Participants

Because this DNP project represented a practice change involving all personnel in this small practice, all staff agreed to participate in the project team. The project team consisted of the family nurse practitioner site champion, a new-to-practice adult-gerontology nurse practitioner, the physician medical director, a certified medical assistant (CMA), and the office manager. Education on the rationale and purpose of the project, and on completing, scoring and evaluating the over-the-counter (OTC) medication survey and GerdQ, was provided to the project team. The providers received additional instruction on evaluating BE risk and completing the post-visit provider survey.

The project team was instructed to provide the OTC medication survey and GerdQ to all primary care patients age 18 years or older who present for a new or annual follow-up visit. Patients younger than 18 years of age, any patient being seen urgently or routine follow-up, and those seen only for opioid dependence were excluded. Patients also had the option to refuse to complete the OTC medication survey and GerdQ tool.

Recruitment

Recruitment began when the project lead approached the site champion during the project development phase. The site champion presented the project idea and general framework to the medical director and obtained her verbal agreement for this clinic to implement the project. After this verbal agreement and project support letter were obtained, an extension of the site contract was pursued.

Project site staff became engaged in this project through informal meetings during the pre-implementation phase. Each team member discussed their role with the project lead, asking questions, and providing implementation process suggestions. Three informal meetings were held so that all team members had the opportunity to discuss the project. The clinic staff were receptive to participation in the project and showed interest in the project by asking questions about the purpose and goals. Providers were interested in seeing how the project impacted comprehensive patient care due to information uncovered by the OTC medication survey. They also expressed uncertainty regarding how the additional assessment would affect their time with patients. In addressing this concern, several processes to monitor time management and workflow issues were considered, including monitoring check-in and check-out times, and delays in getting patients roomed.

Patient completion of the OTC medication survey and GerdQ tool was essential to project success. The CMA provided the tools to all patients meeting the project participant criteria as a part of the routine appointment check-in process. Patients were encouraged to complete the OTC medication survey to ensure a comprehensive medication record, and the GerdQ tool to improve upper GI symptom assessment and management.

Implementation Process

The project implementation period was August 19, 2019, to December 3, 2019. Implementation began with a formal educational PowerPoint presentation (See Appendix N) during a Lunch-and-Learn session the week of August 19, 2019. The rationale and purpose of the project were discussed along with the expected impact the project would have on patient care. Training was also provided on evaluating the OTC medication survey and scoring the GerdQ tool. Providers received additional instruction on assessing BE risk and completing the post-visit

provider survey. Copies of the PowerPoint were given to all project team members to use as a reference. Additional copies were available for nurse practitioner students being precepted at the project site during the implementation period. Several sample GerdQ tools were used to practice the symptom and severity scoring to aid familiarity with the tool. Additional time was allotted for questions following the educational presentation.

Tool implementation began on Monday, August 26th, 2019. The project site was provided with 100 copies of the OTC medication survey listing GI medication categories, with the GerdQ tool in English on the back. The site received 25 copies of the full OTC medication survey with the Spanish GerdQ tool on the back. Additionally, 200 copies of the post-visit provider survey were divided among the providers' offices. The CMA determined which patients met the criteria for tool completion, adding the tools to the routine appointment check-in forms to be completed by the patient. The CMA offered help in completing the forms and informed patients of their purpose if asked. Completed OTC medication surveys and GerdQ tools remained with the patient's check-in paperwork for review by the provider. The GerdQ was scored by providers during the visit, and OTC medications were reconciled following the clinic policy.

During the office visit, providers conducted a BE risk assessment on any patient completing the GerdQ tool. The risk assessment was included at the end of the GerdQ and consisted of a list of the seven criteria for BE risk. The provider was instructed to circle any item that applied. Provider knowledge of GERD management and BE risk evaluation guided changes to the patient's plan of care. The providers completed the post-visit survey following each new or annual follow-up visit. Incomplete OTC medication surveys and GerdQ tools were saved so that participation rates could be tracked. Completed post-visit surveys were stapled to the associated OTC medication survey/GerdQ tool.

At the end of each clinic day, the site champion collected and secured the tools and post-visit surveys in a folder in her office. The office manager and medical director monitored the project's impact on clinic workflow by observing for an increase in the average time between appointment check-in and check-out. Impact on clinic workflow determined whether additional OTC medication groups could be added to the OTC medication survey.

The project lead was available by telephone and e-mail throughout the project. All team members had contact information to reach the project lead with concerns regarding any part of the process. Weekly communication between the project lead and site champion was conducted to discuss successes and opportunities. A follow-up meeting was held with the project team on September 6, 2019, to address issues related to process integration, answer questions, adjust processes, and to review and compile data. The completed GerdQ tools were checked for scoring accuracy. The project lead returned to the clinic every two to three weeks thereafter to collect and record data and provide additional surveys and questionnaires as supplies ran low.

Successful implementation was defined by at least 80% completion of OTC medication surveys and GerdQ tools and by 90% completion of post-visit provider surveys. Accurate scoring of the GerdQ was essential in evaluating the presence and severity of GERD. Therefore, 100% accuracy was expected after the initial two weeks. Successful outcomes included identifying unreported OTC medication use and patients with a new diagnosis of GERD, improving GERD management, and identifying patients at high risk for BE who require screening.

Plan Variation

This QI project had included plan variation at the outset to accommodate the needs of the project site. Concerns were raised during the pre-implementation phase that implementing the full OTC medication survey might impair clinic workflow because the volume of unreported

medications was unknown. The project was initiated using only the three GI categories in the OTC medication survey to address these concerns. Every two to three weeks, the workflow was reassessed. At week eight of implementation, the Pain/Headache OTC medication group was added. Because of time constraints related to practitioner training, no further OTC medication groups were added until week ten. The full OTC medication survey with eight medication categories was introduced for the final three weeks of the project.

The Plan Do Study Act (PDSA) cycle was used to identify process improvement needs throughout the project. The use of the PDSA cycle provided a method to fine-tune processes and address barriers to improvement. Several changes were made during the implementation period to improve data collection and aid in evaluating the GerdQ results and assess BE risk. Changes included providing GerdQ scoring instructions for each provider's office, including the scoring scale for severity and impact on the GerdQ, and BE risk score for men and women on each of the tools.

Summary

Implementation of this QI project was conducted in a small urban family practice clinic over 14 weeks in the Fall, 2019. Thoroughness during the pre-implementation phase and frequent contact with the project team created the foundation for successful implementation. The project team consisted of the entire clinic staff who provided suggestions on the implementation plan, which improved workflow during this phase. The implementation process began with the education of the team on the purpose, process, and evaluation tools. Ongoing reevaluation of the project occurred every two to three weeks. Frequent reassessment allowed the project team to identify factors impacting clinic workflow and accuracy of GerdQ and BE risk scoring so that

processes could be adjusted. This continuous process improvement allowed for successful integration and improved sustainability of this QI initiative.

Chapter Six: Evaluation of the Practice Change Initiative

The intent of this chapter is to examine the effectiveness of the quality improvement (QI) initiative through evaluation of the outcomes data following implementation. Evaluation helped to determine if project goals were met and provided a guide to sustainability. The primary objectives of this project included improving provider knowledge of patients' over-the-counter (OTC) medication use, evaluating gastroesophageal reflux disease (GERD) symptoms and severity, and determining which patients are at high risk for development of Barrett's esophagus (BE).

Participant Demographics

This QI project was implemented in a privately-owned single-office family practice clinic located in urban north-central North Carolina. There were three medical providers in this clinic during the implementation period: the physician medical director and practice owner, a family nurse practitioner serving as site champion, and an adult-gerontology nurse practitioner who was being oriented to the position. The providers were responsible for reviewing the OTC medication survey and calculating the GerdQ score. Based on the survey review and GerdQ score, they then evaluated the BE risk in each patient. Following each encounter, a post-visit provider survey was completed noting the providers' assessment of the information obtained.

During the 14-week implementation period, the OTC medication survey and GerdQ were provided to 82 adult patients who presented to the clinic to establish care or for an annual physical. Of these patients, 79 (96%) completed the surveys. Providers identified 25 (32%) of patients as having GERD based on their history and physical assessment versus 23 (29%) identified with GERD based on GerdQ scoring. Five patients (6%) with an indication for GERD based on their GerdQ score did not indicate self-treatment with OTC reflux medications. A

GerdQ severity score of eight or more indicates a diagnosis of GERD. The impact score is the sum of GerdQ questions five and six, with a score of two or higher indicating GERD.

Demographic information was collected on 62 (78%) of the 79 patient-completed forms. Of the 62 with demographic information, 25 (32%) were age 50 or older, 36 (58%) were male, and 26 (42%) were female. The majority of the patients were Caucasian (62%). The remaining 38% were not identified by their individual race.

Intended Outcomes

Three intended outcomes are addressed within the results of this QI project. The first intended outcome was to improve providers' knowledge of OTC medication use and frequency among their patients. The OTC medication survey was utilized to evaluate this outcome. Secondly, identifying patients with GERD was necessary before addressing the third goal. This was accomplished through the use of the GerdQ tool. The final outcome was identifying patients at high risk for the development of BE. A BE risk assessment checkbox was included on the GerdQ tool. The long-term goal of this project was to establish a process to identify patients at high risk of BE. Screening the appropriate patients for this precancerous condition is an essential step in esophageal adenocarcinoma prevention.

Findings

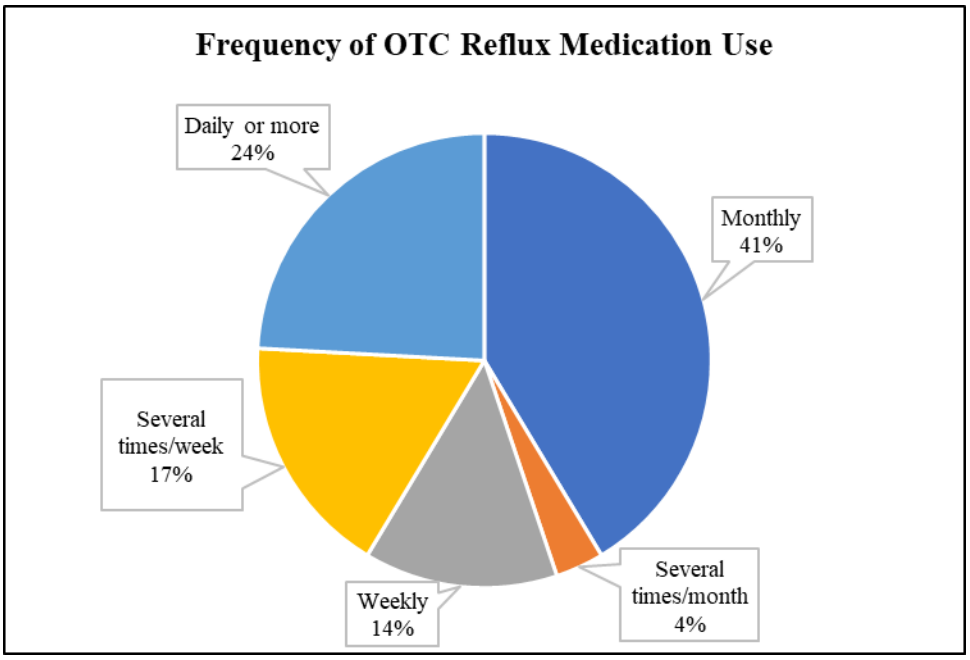
OTC medication survey. Of the 79 patients completing **t**he OTC medication survey, 51 (64%) reported taking at least one OTC medication monthly. During the first ten weeks of implementation, the survey included three gastrointestinal (GI) medication groups. Of the 61 patients who completed the survey with three GI medication groups, 38 (63%) indicated using a GI OTC medication at least monthly.

During week eight, a fourth OTC medication category was added to include OTC pain medications. Ten out of 79 patients completed the four-category survey. Beginning at week 11, the full OTC medication survey, including all eight categories, was introduced. Eight patients out of the 79 completed the eight-category survey from weeks 11 through 14.

In evaluating the heartburn/indigestion/reflux medication category, 29 (37%) of the 79 patients responded to using OTC medications at least monthly, and 16 (20%) reported using them weekly or more often. Seven (10%) patients reported taking these medications at least daily. OTC pain medication use was also evaluated due to the impact on the GI system and the potential for drug-drug interactions. There were 18 surveys that included the OTC pain medication category with nine patients (50%) identifying at least monthly use. Five of the 18 patients (28%) used OTC pain medication several times per month or more. Frequent OTC pain medication use, defined as at least weekly use, was reported by two patients (11%).

Post-visit provider surveys were completed for each of the 79 visits where patients completed the OTC medication surveys. Providers reported 18 (23%) of the 79 OTC surveys identified a new health problem to be addressed. Based on the OTC medication survey, providers reported same-day treatment plan changes during 20 (25%) visits. Treatment plan changes included new or altered medication regimens, tests, lifestyle modifications, and patient education.

GERD symptoms and severity. OTC medication used for self-treatment of reflux or heartburn was identified by 29 (37%) of the 79 patients (see Graph 1). Of the 29 patients using OTC heartburn medications, 13 (45%) used them monthly or several times per month. Weekly use or more often was indicated by 9 (31%) patients, and seven (24%) patients indicated the use of OTC heartburn medications at least daily.

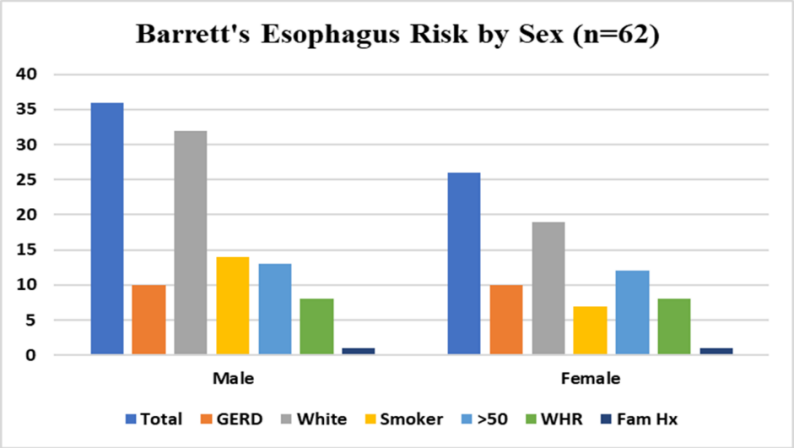


Graph 1. Frequency of OTC reflux medication use (n=29)

When comparing the 13 patients reporting the use of OTC medication several times per month or less, 4 (31%) had GERD based on the GerdQ severity score. Of the 16 patients reporting weekly or greater OTC medication use, 14 (87%) had GERD based on the GerdQ severity score. Among the 29 patients indicating OTC reflux medication use at least monthly, 18 (62%) could be diagnosed with GERD based on their GerdQ severity or impact score. Four patients (14%) were considered to have GERD based on the GerdQ impact score alone. Of these four patients, two had a GerdQ severity score of five, and two had a score of seven. All four patients meeting the GERD diagnostic criteria based on the GerdQ impact score indicated they took OTC reflux medications weekly or more to manage their symptoms. The mean GerdQ severity score was 8.55, and both the median and mode were 8.

Barrett's esophagus risk. BE risk was not evaluated on every patient completing the OTC medication survey and GerdQ tool. Providers included demographic information related to

BE risk factors on 62 (78%) of the 79 patient-completed forms (see Graph 2). In reviewing the demographic findings and BE risk factors, a diagnosis of GERD was associated with ten (28%) of the men and ten (38%) of the women. Caucasian race accounted for 32 (89%) men and 19 (73%) women, and 14 (39%) of the men were smokers versus seven (27%) of the women. Patients 50 years or older comprised 36% (13) of the male group and 46% (12) of the female group. Waist-to-hip ratio (WHR), another indicator of BE risk, was seen in 8 (22%) men and 8 (31%) women. Of the 62 patients, a family history of BE or esophageal cancer was noted in one man (3%) and one woman (4%). The male patient with a family history of BE or esophageal cancer was considered high risk for BE but had not yet reached age 50. The female also did not meet the criteria for BE screening. Aside from GERD, her only additional risk factor was Caucasian race.



Graph 2. **Individual risk factors for Barrett's Esophagus by sex**

Table 1 provides a summary, highlighted in yellow, of patients categorized as high risk for BE. High risk is defined in men with GERD having two or more additional risk factors, and in women with GERD having four or more additional risk factors. Of the ten men with GERD, 9 (90%) were considered high risk for BE, with four (40%) who were age 50 or older. These four men met the screening criteria for BE during this QI project. Three were referred to

gastroenterology for evaluation. Of the ten women with GERD, none were considered high risk for BE. BE screening is not recommended for anyone less than age 50 years unless red flag symptoms such as dysphagia are present. Red flag symptoms were not identified in any of the patients completing the OTC survey or GerdQ. Based on the 79 post-visit provider surveys, five patients (6%) were identified as being high risk for BE. Nine (11%) were identified using the BE risk assessment box located on the GerdQ tool.

Table 1.

Aggregate Barrett's Esophagus Risk Factors by Age and Sex

BE Risk Factors	Male	Female	BE Screening (>49 yrs)
GERD + 0	0	1	
GERD + 1	1	1	
GERD + 2	3	4	
GERD + 3	5	4	3
GERD + 4	1	0	1
GERD + 5	0	0	

Yellow boxes indicate BE high-risk

Summary

Findings from the QI project implementation provided valuable information that might not otherwise have been identified. The OTC survey tool identified that 64% of this clinic's patients reported using OTC medications to self-treat. With this information, more focused evaluation of GERD using the GerdQ tool was possible. Patients self-treating GERD symptoms at least monthly comprised 36% of the respondents, and 46% of these respondents met the criteria for a diagnosis of GERD based on the GerdQ scores. Identifying patients with GERD, the primary risk factor for BE, is essential to determining BE risk. Nine patients were identified as high-risk for BE development, and four of these met the screening criteria of being 50 years or older. This multistep process is one measure that primary care clinics can use to offer holistic care and reduce risk for their patients.

Chapter Seven: Implications for Nursing Practice

The DNP Essentials, a guide set out by the American Association of Colleges of Nursing (AACN, 2006), are the foundation upon which this practice doctorate rests. The eight components discussed in this chapter comprise the measured outcomes and competencies which each graduate must meet to be conferred the degree of Doctor of Nursing Practice (DNP). These essential components are encompassed within the DNP scholarly project. The process begins with the identification of a practice problem, moves through information synthesis, project development, and implementation, and culminates with the evaluation of the project outcomes. The project paper is the capstone of the DNP program and denotes the written evidence of the accomplishment of the DNP Essentials.

Practice Implications

The eight DNP essentials provide a framework that informs evidence-based practice throughout this DNP project and future projects. The findings of this DNP project had several practice implications, including identification of patient self-medication practices and improvement in the identification of at-risk patients for Barrett's esophagus (BE).

Essential I: Scientific underpinnings for practice. Scientific knowledge translation and application through nursing theory are at the core of this essential (AACN, 2006). Evidence and research from a wide range of sciences, along with nursing theory, frame and guide the development of evidence-based practice measures to improve practice and patient outcomes and quality of care (AACN, 2006).

This quality improvement (QI) project brought together the problem of an escalating incidence and mortality from esophageal adenocarcinoma (EAC), lack of screening guidelines for BE, and a lack of understanding of patient self-medication for gastroesophageal reflux

disease (GERD) to develop a clinic policy designed to improve identification of BE risk. There is disparity among gastroenterology organizations regarding BE screening. When coupled with a provider's lack of understanding of their patient's GERD self-treatment, patients who are at risk for BE are overlooked, leading to identification only when alarm symptoms occur, possibly after esophageal adenocarcinoma (EAC) has developed. A review of the available literature identified reasons that patients omit disclosure of self-medication and measures to improve disclosure, such as structured interviewing during medication reconciliation (Sarzynski et al., 2014) and use of prompts (Jarrett, Cochran, Baus, & Delmar, 2019). Additional literature reviewed identified the GerdQ as a validated method to evaluate the presence and impact of GERD in primary care (Jones et al., 2009). The preceding information provided the foundation of this QI project with a goal of identifying patients at risk of developing BE who may need to be screened.

The ability to translate evidence and facilitate evidence-based practice change is the hallmark of the DNP-prepared nurse. Identification of practice and organization problems and their related concepts, and looking at issues from multiple perspectives are valuable skills when developing a practice change project. Visualization of concept relationships through concept mapping further defines the problem and suggests potential solutions. Evidence-based practice change is a complex, multidimensional process that is best guided using a framework based on sound theory. This project uses both the Iowa Model for Evidence-based Practice Change and Lewin's Change Theory. Using a step-wise process, the Iowa Model guides the quality improvement process. When used in conjunction with Lewin's Change Theory's unfreezing, movement, and refreezing processes, implementation and integration will achieve greater success.

Essential I provides the DNP-prepared nurse the ability to identify, evaluate, and translate available evidence into practice. Understanding nursing and change theories provide a solid foundation for the implementation and integration of practice improvement initiatives. When applied in conjunction with quality improvement models, healthcare practices and patient outcomes are improved.

Essential II: Organization and systems leadership for quality improvement and systems thinking. Essential II prepares the advanced practice nurse to develop practice improvement programs to improve quality and safety within the context of patient populations, organizations, and communities (AACN, 2006). Leadership involves the ability to clearly articulate ideas, incorporate financial planning and budgeting, evaluate health policy, and analyze risks and benefits (AACN, 2006). All of these skills are essential during project development.

This DNP project improved patient safety and care quality in several ways. Improved provider knowledge of patient over-the-counter (OTC) medication use has the potential to reduce drug-drug interactions and adverse reactions among their patient population. Additionally, provider knowledge of a patient's diagnosis of GERD accompanied by identification of other BE risk factors will facilitate the optimization of treatment and referral for screening when appropriate, thus reducing morbidity and mortality.

In the pre-implementation phase of this QI project, a SWOT analysis was completed and a budget prepared. Potential weaknesses were identified and included increased provider workload and lack of EHR integration. Strengths included site champion and clinic staff interest, low cost to the practice, and acknowledgment of potential to improve quality of care. Open

channels of communication were maintained throughout the process through on-site meetings, telephone conversations, and electronic communication, including text messaging and e-mail.

Essential III: Clinical scholarship and analytical methods for EBP. Scholarly activities in DNP education involve translation of evidence derived from research into clinical practice. Essential III requires analysis of existing and new research and applying it to solve practice, organization, or system problems to improve outcomes (AACN, 2006). Information technology is also essential in program and project development, analyzing data, and evaluating outcomes (AACN, 2006).

The literature review for this project found a practice gap in the identification of BE risk and also in screening recommendations. No nationally recognized standardized tool is available to measure BE risk, nor are the association guidelines clear on who should be screened. A practice barrier existed in identifying patients with GERD at this clinic as patients were not always forthcoming with their OTC medication use, and no standardized practice was in place to obtain this information. Additional literature was reviewed to determine evidence-based measures that could be employed to improve knowledge of OTC medication use, and validated tools to evaluate for the presence of GERD. Recommendations regarding BE risk assessment from several GI societies were analyzed to develop an evidence-based tool for determining who was at highest risk and would most benefit from screening. Synthesis of the available evidence initiated the development of an OTC medication survey, use of the GerdQ to diagnose and evaluate the severity and impact of GERD, and design of a BE risk assessment tool.

Analysis of data throughout the project timeframe and dissemination of project findings is vital to ongoing quality improvement and healthcare outcomes. The interim project findings were reviewed with the project site clinicians during several PDSA cycles, and revisions to the

project plan were made each cycle. Project findings were disseminated through a final report and presentation to the clinic staff, and by virtual podium presentation at the East Carolina University College of Nursing. Upon completion, the DNP scholarly project paper was uploaded to the ScholarShip, East Carolina University's institutional repository of scholarly works.

Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare. The use of information technology to improve the quality of patient care and clinical outcomes is the basis for Essential IV. Proficiency in information systems, electronic health records (EHR), and data management tools is indispensable to the DNP-prepared nurse. The clinic EHR was used to identify baseline aggregate data about the clinic's patient population, including the number of patients seen, payer sources, and general patient demographics. Microsoft® Office and Excel were used to compile and analyze, and display data using tables, charts, and graphs. Microsoft® PowerPoint was used to create an initial educational presentation for the project team and final poster displaying the data and project outcomes.

Essential V: Healthcare policy for advocacy in healthcare. Healthcare policy and advocacy are crucial to meeting the needs of patients, systems, and communities, no matter the size (AACN, 2006). The DNP nurse is prepared to meet these needs through policy and program development to reduce healthcare disparities, improve health, and prevent illness (AACN, 2006). The short-term goal of this project was to improve patient health and prevent illness by identifying OTC medication use, optimize treatment of GERD, reduce GERD impact on quality of life (QOL), and to improve risk assessment for BE. The long-term goal was to prevent the morbidity and mortality caused by EAC. Medication reconciliation in the primary care setting is a quality and safety metric set by both the Centers for Medicare and Medicaid Services (CMS)

and the Joint Commission (TJC). The short and long-term goals were met through the development of a clinic policy that advocated for improved medication reconciliation with the inclusion of frequently used OTC medications added to the EHR. Additionally, a strategy to evaluate GERD and its impact on QOL, along with BE risk assessment, allows clinicians to provide patient-centered recommendations for improvements in health and prevention of disease through disease management measures and screening.

Essential VI: Interprofessional collaboration for improving patient and population health outcomes. The ability to both lead and collaborate are defining characteristics of the DNP-prepared advanced nursing practice. These characteristics occur within interdisciplinary teams across multiple healthcare settings and are essential in today's complex healthcare environment (AACN, 2006). Teamwork among the site champion, project lead, project faculty, and clinic team was crucial in the development, implementation, and evaluation of this DNP QI project. Communication was effective among the entire project team and was carried out both in person and electronically. Effective communication, education, and collaboration facilitated team involvement and buy-in to the process and understanding of the changes in their day-to-day work. The site champion and clinic team were involved in interim project evaluation and process improvement throughout implementation. Collaboration with the site champion occurred during each PDSA cycle, and input was sought from affected team members when changes were made. Multimodal communication and frequent collaborative efforts facilitated teamwork and kept the QI project on course

Essential VII: Clinical prevention and population health for improving the nation's health. Health promotion, risk reduction, and disease prevention are hallmarks of advanced practice nursing (AACN, 2006). Analysis of existing data identify GERD and BE incidence

increasing over the last four decades (Runge et al., 2015) with a corresponding seven-fold increase in EAC (Hang et al., 2018) which has an 18% five-year survival rate due, in part, to late-stage diagnosis (Peery et al., 2015). There are no established screening guidelines for BE, and gastroenterological societies have not come to a consensus on who is at highest risk for BE development, creating a gap in care. Additionally, GERD, the primary risk factor for the development of BE, often goes undiagnosed due to the ease of self-treatment with numerous OTC medications.

This project was designed to identify patient self-treatment of reflux symptoms, utilized a validated diagnostic tool for GERD, and provided a BE risk assessment tool for providers to prompt appropriate screening for BE. Patients with new or undertreated GERD have improved QOL when their GERD symptoms are effectively managed, along with a reduction of risk of developing BE (Gikas and Triantafillidis, 2014). The results of this QI project found that education of providers on BE risk factors and the use of a simple risk factor assessment tool improved identification of patients who require risk factor modification and screening. In the future, BE risk assessment should be conducted on any patient with a diagnosis of GERD at the time of referral for colorectal cancer screening or surveillance so that concurrent BE screening can be completed if indicated.

Essential VIII: Advanced nursing practice. Essential VIII encompasses advanced assessment and clinical judgment, and development of interventions and processes through analysis and synthesis of research to accomplish evidence-based care and improved quality and outcomes (AACN, 2006). Therapeutic relationships, leadership, and collaborative practice are utilized to educate, mentor, and guide individuals and teams to facilitate the quality improvement of complex problems (AACN, 2006).

Analysis and synthesis of the current literature provided the basis for conceptualization of a process to identify patients at high risk for development of BE by first determining who is self-treating reflux symptoms and then using the GerdQ tool to diagnose GERD and its severity and impact on QOL. Implementation of this process involved building and leading an interprofessional team to close a gap in care through OTC medication reconciliation in this small urban primary care clinic. Educational and assessment tools guided the clinicians' evaluation and decisions regarding the need for treatment modification and BE screening.

Summary

The AACN's DNP Essentials are the foundation of the advanced practice nurse's education, guiding scholarly work to improve healthcare for individuals, systems, and communities. Analysis and synthesis of research lead to the development of new evidence-based methods to improve quality and safety in healthcare. The use of information systems and technology is essential for tracking and analyzing data and provide a means for rapid reevaluation and revision of project plans. Interprofessional collaboration, communication, and teamwork are crucial for managing complex healthcare problems. A sound understanding of each of the DNP Essentials allows DNP-prepared nurses to translate evidence into practice, to improve quality and safety, reduce disparities, promote health, reduce risk, and prevent diseases.

Chapter Eight: Final Conclusions

The intent of this DNP quality improvement (QI) project was to improve the identification of patients at increased risk for development of Barrett's esophagus (BE) in an urban family practice in N.C. The implementation of the OTC medication survey and GerdQ, along with provider-identified BE risk factors, was effective in identifying at-risk patients among the 79 patient respondents. This chapter will review the significance, strengths, and limitations of this QI project, and practice recommendations will be discussed

Significance of Findings

There were several clinically significant findings identified as a result of this QI project. The over-the-counter (OTC) medication survey showed monthly or greater OTC medication use in 64% of the patients completing the survey. This led provider identification of a new clinical problem to be addressed in 23% of respondents and a change in the treatment plan in 25% of respondents. The data obtained from this small group of patients serves to identify potential gaps in care caused by previously unknown OTC medication use.

The stated purpose of this QI project was to increase the identification of patients at risk for BE and to prevent esophageal adenocarcinoma (EAC). Identification of BE risk must first start with assessing its primary risk factor, GERD. In evaluating the responses to the OTC medication survey, 32% of the 79 patients identified using OTC medications to treat their reflux symptoms at least monthly, and 62% of these patients were diagnosed with GERD. Based on this information along with additional BE risk factors, 11% were found to be at high risk, with 5% meeting the criteria for a screening endoscopy. These findings suggest that the tools selected, when used together, are effective in identifying patients who are at risk in the primary care setting.

Project Strengths and Weaknesses

Several strengths were identified, among them were provider and staff buy-in and interest in process improvement to improve holistic patient care. Because all project partners had a stake in the process, interprofessional collaboration was enhanced. This allowed improved understanding and buy-in of the project and process, aiding in effective communication when project changes were required. The use of patient-completed tools reduced the amount of time staff spent collecting needed information. The GerdQ tool was selected for its simplicity of use and high specificity for GERD. Instruction on the project, written guidance on the use of tools, and frequent contact with the on-site QI project team assisted in keeping everyone involved during the 14-week implementation period.

The project was not without its weaknesses. Providers were responsible for reconciling each patients' medication list leading to increased appointment time spent documenting. The appointments available for inclusion during the project were limited due to the AGNP provider being in training, which limited her participation. The GerdQ and BE risk tools required revision several times to improve scoring and score assessment, which led to several missed opportunities for GERD treatment optimization. The inability to integrate any of the project steps electronically, or to easily extract information from the EHR was a barrier as well.

Project Limitations

The number of patients included in the QI project was limited to patients new to the practice or presenting for annual physicals, therefore, limiting the identification of the scope of the problems being addressed. Because the number of ancillary office staff was limited at this practice, providers were responsible for the increased paperwork required to complete the QI

project process. Delayed introduction of the full OTC medication survey limited the ability to determine the full scope of OTC medication use among the patients who completed the surveys.

Project Benefits

This project provided several benefits to this family practice allowing them to provide more comprehensive care for their patients. Providers gained an understanding of the scope of OTC medication use among a portion of their patient population. This knowledge prompted immediate changes to treatment plans and identified new health issues that needed to be addressed. The long-term outcome is that patient care will be more holistic as providers become fully informed about the measures patients are using to manage their health issues on their own.

One of the challenges of decreasing rates of EAC is identifying methods for screening those at highest risk for the development of BE, its precursor lesion. This QI project identified one successful method that could be employed in any practice to guide BE risk assessment. Early screening and identification of BE carries the added benefit of reducing the estimated $184,000-$250,000 costs associated with a diagnosis of EAC (Mariotto, Yabroff, Shao, Feuer, & Brown, 2011). The use of a validated tool, the GerdQ, to determine the presence or undertreatment of GERD and then identifying additional risk factors for BE led to the optimization of GERD treatment and referral for BE screening in several patients. Appropriate screening of at-risk patients improves the odds of detecting BE and early EAC, preventing long-term consequences, increased cost burden, and high mortality of late-stage esophageal cancer. These interventions served to meet the Institute for Healthcare Improvement's Triple Aim objectives of improved per-capita costs, experience of care, and population health (2020).

Practice Recommendations

Based on QI project findings, several practice recommendations should be considered. The use of the full OTC medication survey should continue. The information obtained from the OTC medication survey is useful beyond the scope of this project, providing to an opportunity to identify OTC medication misuse, drug-drug and drug-disease interactions, and previously unknown health concerns.

One recommendation is to incorporate measures that would streamline the information-gathering process. Patients should receive pre-appointment forms by mail or online for completion at home to improve the accuracy of the OTC medication survey. The integration of these forms in the electronic health record through the patient portal prior to each visit may provide a way to streamline the process and allow for provider review during pre-visit planning.

Use of the GerdQ and BE risk tools as a standardized assessment should continue for any patient with a diagnosis of GERD and anyone using OTC reflux medications monthly or more often. Early management of GERD and improving modifiable risk factors will reduce patients' risk of developing BE. Patients referred for a colonoscopy at age 50 or older should be evaluated for BE risk at the time of referral as a standard protocol. Those who are identified as high-risk should be referred for a screening esophagoscopy along with the colonoscopy. Finally, patients not meeting BE screening criteria but who have a family history of esophageal carcinoma or BE should be evaluated. Assessment should include the degree of relationship and age at the time of diagnosis, and referral to GI may be warranted based on the provider's clinical judgment.

Final Summary

The prevalence of Barrett's esophagus and esophageal adenocarcinoma is increasing in the U.S. at an alarming rate. With a five-year survival rate of 18% for EAC and no national

standardized guidelines for screening for BE, it is up to the primary care practitioner to evaluate disease risk and determine the appropriate recommendations. This evaluation is made more difficult due to patient self-treatment of GERD symptoms with OTC medications leaving the provider unaware of the potential risk. With the introduction of an OTC medication survey, a validated GERD evaluation tool, and BE risk factor checklist, this QI project demonstrated an effective way for the practitioner to evaluate a patient's risk and develop an appropriate treatment plan to ameliorate the risk or send for a referral. Ongoing utilization of these tools and implementing a BE screening protocol are essential steps in improving holistic care and reducing the long-term consequences of esophageal cancer.

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Appendix A

Literature Review

Article	Level of Evidence	Data/ Evidence Findings	Conclusion or Summary	Use of Evidence in EBP Project Plan
Albert, S. M., Bix, L., Bridgeman, M. M., Carstensen, L. L., Dyer-Chamberlain, M., Nefesh, P. J., & Wolf, M. S. (2014). Promoting safe and effective use of OTC medications: CHPA-GSA national summit. *The Gerontologist, 54*(6), 909-909. doi:10.1093/geront/gnu034	VII	Summit meeting conducted by the Gerontological Society of America (GSA) and CHPA to promote safe/effective use of OTC meds by looking at the way these meds are used especially by older adults	Panel looked at health literacy, decision making, provider roles in decisions and OTC behaviors, technologies to promote optimal use; found that younger pt. more likely to get advice from friends/family; older adults from pharmacist or provider; clinicians need to ask questions about OTC med use to address issues and misperceptions re: OTC use; recommend structured interviewing to learn about OTC behaviors and get info into EHR	Workgroup designed to establish the questions that need to be addressed and areas for further research by looking at what is known and where there are gaps; one gap is how providers get information on OTC medications and how to incorporate into HER

American Association of Colleges of Nursing. (2006). The essentials of doctoral education for advanced nursing practice. Retrieved from: https://www.aacnnursing.org/Portals/42/Publications/DNPEssentials.pdf	VII	Background information on the DNP Essentials	Details the eight required essentials required to meet doctoral education for advanced nursing practice.	Used in chapter seven to define each essential while providing exemplars from the project.
American Association of Nurse Practitioners. (2019). What's a nurse practitioner (NP)? Retrieved from: https://www.aanp.org/about/all-about-nps/whats-a-nurse-practitioner	VII	Background on function of nurse practitioner.	Provide background on purpose and function of NP.	General background on NP purpose and function as it relates of coordination of patient care.
Bolier, E. A., Kessing, B. F., Smout, A. J., & Bredenoord, A. J. (2015). Systematic review: Questionnaires for assessment of gastroesophageal reflux disease. *Diseases of the Esophagus*, *28*(2), 105-120. doi:10.1111/dote.12163	I	Systematic review of all current GERD questionnaires to provide an overview categorized by how GERD is assessed. 65 questionnaires were assessed	Questionnaires were categorized by their assessment type, some fit more than 1: Generic - 3; esophageal GERD symptoms - 33; extra-esoph symptoms - 3; response to treatment - 14; diagnosis - 7; quality of life - 18; infants/children - 8; others - 6. No single questionnaire useful to measure all dimensions.	QI project designed to assist diagnosis of GERD in clinic setting. 2 questionnaires identified as applicable to the project: GerdQ and RDQ, both validated and translated into a number of languages. Additional information on specifics of validity would be helpful here, but review provided enough

				information to r/o tools that would not be useful in this project.
Consumer Healthcare Products Association. (2019). Statistics on OTC use. Retrieved from: https://www.chpa.org/MarketStats.aspx	VII	CHPA is trade association representing manufacturers and marketers of OTC products	Provide statistics for OTC medication use and value; also includes regulatory info, public policy, and consumer education (https://www.knowyourotcs.org/)	Useful for statistics on OTC medication use and perceived benefits; it is a trade association website so there is bias

Crews, N. R., Johnson, M. L., Schleck, C. D., Enders, F. T., Wongkeesong, L., Wang, K. K., . . .Iyer, P. G. (2016). Prevalence and predictors of gastroesophageal reflux complications in community subjects. *Digestive Diseases and Sciences, 61*(11), 3221-3228. doi:10.1007/s10620-016-4266-3	II	Randomized trial looking at clinical risk and predictors of BE found male sex, and central obesity to be independent risk factors with increased risk when 3+ risk factors present regardless of presence of GERD. Increased risk was independent of presence of GERD	BE risks are well-defined and cumulative with odds of EE or BE 3.7 x higher with 3-4 risk factors, and 5.7 x higher with 5+ risk factors; male sex and central obesity are independent risk factors, age > 50, GERD, Caucasian race, smoking, and fam history also increase risk; ETOH use not a risk.	Most screening for BE focuses on presence of GERD but in this study prevalence of EE was similar between those with and w/o GERD although those w symptoms had higher grades of esophagitis. Central obesity identified by waist: height ratio vs. BMI. Limitations include study conducted on population of age 50 or older and 98% Caucasian both known as risks for BE but limits application of results to other racial groups.
Cullen, L., & Sigma Theta Tau International. (2017). *Evidence-based practice in action: Comprehensive strategies, tools, and tips from the University of Iowa Hospitals and Clinics.* Indianapolis, IN: Sigma Theta Tau International.	V	Book discussing all aspects of implementation of evidence-based practice using the Iowa Model for Evidence- based Practice Change	Iowa Model is chosen framework for this scholarly project. Book provides thorough background and step-by-step detail for implementation of practice change using this model.	Will refer back to this book for strategies and tools for implementation of project.

Gikas, A., & Triantafillidis, J. K. (2014). The role of primary care physicians in early diagnosis and treatment of chronic gastrointestinal diseases. *International Journal of General Medicine, 7,* 159. doi:10.2147/IJGM.S58888	VI	Discusses the role of PCPs to diagnose and manage chronic GI diseases. Discussion of the role of GI cancer screening; the burden of disease and impact on PCP practice	Information on esophageal cancers and risk mitigation; GERD diagnosis and disease management, refractory symptoms, lifestyle modifications for treatment and impact on QOL	Uses 2014 British guidelines for BE recommendations which differ from ACG and AGA; for GERD suggest assessing compliance to meds/lifestyle mods before changing regimen, use of PRO tools to eval effectiveness
Grusell, E. N., Mjörnheim, A., Finizia, C., Ruth, M., & Bergquist, H. (2018). The diagnostic value of GerdQ in subjects with atypical symptoms of gastro-esophageal reflux disease. *Scandinavian Journal of Gastroenterology, 53*(10-11), 1165-1170. doi:10.1080/00365521.2018.1503708	IV	Cohort study design used to determine the value of using the GerdQ when atypical symptoms of GERD are present; when atypical symptoms are the main presenting signs of GERD sensitivity is low(36%) and specificity is high (80%). Atypical symptoms evaluated were globus, cough, and dysphagia	Study subjects completed GerdQ and then underwent 24-hr pH monitoring. Optimal cut-off score was 8 or higher for dx GERD. Use of the GerdQ with atypical symptoms might have value in ruling out GERD prompting consideration of other differentials; study validates GERD in typical symptoms (sensitivity 84%, specificity 57%)	Dysphagia is considered an atypical symptom in this study. All current guidelines consider this an alarm symptom which should prompt the provider to send for endoscopy. Strengths include the size of the study (n=646) and tested pt. with and without typical and atypical symptoms.

Gyawali, C. P., Kahrilas, P. J., Savarino, E., Zerbib, F., Mion, F., Smout, A. J., . . . Roman, S. (2018). Modern diagnosis of GERD: The Lyon consensus. *Gut*, *67*(7), 1351-1362. doi:10.1136/gutjnl-2017-314722	I	Discussion of prevalence and impact of GERD and modern methods to make a definitive diagnosis vs empirical diagnosis. Clinical history, questionnaires such as the GERDQ , and PPI trials for symptom management are endorsed by societal guidelines for initial identification and management of GERD in primary care, but are not as sensitive or specific as ambulatory pH and impedance testing or endoscopy with biopsy	GERD symptoms are heterogeneous making diagnosis a complex process. endoscopy with biopsy should be considered in PPI non-responders or pts with atypical symptoms. If endoscopy is normal reflux testing should follow. Symptom assessment and GERD questionnaires are helpful in monitoring treatment outcomes.	The initial diagnosis of GERD in primary care is often based upon symptom assessment and response to treatment with PPIs. Use of a validated GERD questionnaire is helpful in the initial diagnosis of GERD and in follow-up to evaluate treatment effectiveness in patients with the typical symptoms of reflux, heartburn, and regurgitation. Patients with atypical or alarm symptoms should be referred to gastroenterology for testing and confirmatory diagnosis. Lack of access to specialty care is a barrier for confirmatory diagnosis.

Hang, T. P., Spiritos, Z., Gamboa, A., Chen, Z., Force, S., Keilin, S., . . . Willingham, F. (2018). The epidemiology of esophageal adenocarcinoma in the United States: Presidential poster award: 333. *American Journal of Gastroenterology, 113*(Supplement), S185-S186. doi:10.14309/00000434-201810001-00333	VI	Descriptive study of SEER data on epidemiology of esophageal adenocarcinoma and other epithelial cancers looking at the change in incidence over time.	Data was reviewed between 1973 and 2014 finding a change in incidence of 733% during that time period with an average annual percent change of 5.4%. The annual percent increase plateaued during the last 10 years reviewed. Additional findings showed that identification of early stage EAC was stable at 21%.	Used as background of the problem related to EAC showing a seven-fold increase in incidence over the past four decades. Additionally, only 21% of patients are identified in the earliest, most treatable stage.
Health Resources and Services Administration. (n.d.). Readiness assessment & developing project aims. Retrieved from: https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/readinessassessment.pdf	VII	Background on organization readiness for change related to quality improvement.	Information on assessing readiness for change and developing project aims when planning a QI project. Part of the HRSA's QI Toolbox.	Used in paper to identify the three characteristics that define organizational readiness: leadership commitment to QI, clinician acknowledgment of the value of QI, and the ability to collaborate.

Holt, K. M., & Thompson, A. N. (2018). Implementation of a medication reconciliation process in an internal medicine clinic at an academic medical center. *Pharmacy, 6*(2), 26. doi:10.3390/pharmacy6020026	VI	Implementation of a med reconciliation process to be completed by nurses and MA's by reviewing med list with each pt. and updating noting discrepancies and then providing updated list for provider review and approval	Discrepancies include completed meds still on list, changed meds still on list, dosing errors, duplications, and omissions; most common discrepancy was continued listing of med no longer taking. Accuracy of medication record involves patient participation: bringing all meds in; using only 1 pharmacy, knowledge of all meds taken	Obtaining accurate med list can be accomplished but is time-consuming and resource intensive. Team reconciliation (nurse, pharmacist, provider) provides best result, but likely not sustainable; did not break down what meds were frequently omitted (occurred in 7-24% of records); Based on TJC pt. safety goal for med reconciliation in ambulatory care; good background info
Institute for Healthcare Improvement. (2020). Triple Aim for populations. Retrieved from: http://www.ihi.org/Topics/TripleAim/Pages/Overview.aspx	VII	Overview of the Triple Aim criteria for healthcare improvement.	Triple Aim objectives include improved population health, cost, and patient experience.	Measures that reduce cancer incidence such as screening for BE risk, will improve population health, reduce per incidence cost, and improve patient satisfaction with care.

Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing, 14*(3), 175-182. doi:10.1111/wvn.12223	VI	Study of the revised Iowa Model to evaluate and validate for use as a tool for implementation of EBP across variable settings	Needed revisions were identified by users and then once rewritten was evaluated and validated by participants of the 22nd National EBP Conference.	Updated changes for EBP practice change in current healthcare environment. Toolkit will be used throughout this scholarly project.
Ireland, C. J., Laws, T. A., Gordon, A. L., Thompson, S. K., & Esterman, A. (2018). General practitioners' use of risk prediction tools and their application to Barrett's oesophagus: A qualitative study. *Journal of Primary Health Care and General Practice, 2*(1), 1-7.	VI	Semi-structured interviews with general practitioners and a GI provider to evaluate use of risk prediction tools for BE in practice	Barriers and enablers identified: barriers include time poverty, tool format, relevance, remembering to use, and reduced autonomy of clinical decisions; enablers: simple format, memory prompt, clear guide, keeps focused, and easy to access	Provides a guideline for development of assessment tools for use in clinical practice. When evaluating the use of any tool should try to avoid barriers and incorporate enablers
Iyer, P. G., & Kaul, V. (2019). Barrett esophagus. *Mayo Clinic Proceedings, 94*(9), 1888-1901. doi:10.1016/j.mayocp.2019.01.032	VII	Article reviews BE and EAC epidemiology, risk, management, progression, and survival rate trends	Evaluation and treatment methods for BE and EAC are improving but identifying patients at risk who should be screened remains a barrier to improving survival rates. There continues to be little agreement among US and European	Risk assessment and risk stratification continue to be a barrier for screening for BE and this limits the improvement in EAC survival rates.

			GI societies on what factors constitute high risk and who should be screened.	
Jarrett, T., Cochran, J., Baus, A., & Delmar, K. (2019). MedManage: The development of a tool to assist medication reconciliation in a rural primary care clinic. *Journal of the American Association of Nurse Practitioners*, (forthcoming). doi:10.1097/JXX.0000000000000197	VI	MedManage, developed in rural primary care clinic to help improve medication reconciliation in high risk patients; Use of tool increased OTC reporting by 82%, PRN reporting by 3%, and herbals and supplements by 28%	Tool consists of body diagram and symptom prompts asking pt. to list meds taken for that symptom over past 2 weeks. Also asks pt. to list herbals, supplements, skin care products, and dietary supplements used. Some pts required extensive assistance to complete form; some pts reluctant to provide info on OTC use	Pictures used to help low-literacy pts, but still had trouble completing the form. Useful as a prompt for patient recall of OTC medication use; limitation small non-generalizable study; provides data that prompting may help pt. recall OTC medication use.

Jones, R., Junghard, O., Dent, J., Vakil, N., Halling, K., Wernersson, B., & Lind, T. (2009). Development of the GerdQ, a tool for the diagnosis and management of gastro-oesophageal reflux disease in primary care. *Alimentary Pharmacology & Therapeutics, 30(10), 1030-1038. doi:10.1111/j.1365-2036.2009.04142.x*	IV	Development of the GerdQ, a patient-centered self-assessment tool for diagnosis and management of GERD with validation studies. Seminal work for this tool.	GerdQ tool found to be sensitive at 65% and specific at 71% for GERD; high enough validity for use in non-GI setting for presumptive diagnosis of GERD; also useful in assessing severity of symptoms and response to treatment	Seminal work. Tool developed through combination of other GERD symptom questions. Form is 6 questions, easy to use, can be completed by patient, scoring is straight forward. AstraZeneca is the owner of this tool.
Kellerman, R., & Kintanar, T. (2017). Gastroesophageal reflux disease. *Primary Care: Clinics in Office Practice, 44*(4), 561-573. doi:10.1016/j.pop.2017.07.001	VI	Background of GERD and related motility disorders, complications, and management	Considers PPIs first line tx with 80% response rate; includes in-depth discussion of the different acid reducers; management of refractory GERD is discussed	Additional background on GERD and management in primary care
Kuipers, E. J., & Spaander, M. C. (2018). Natural history of Barrett's esophagus. *Digestive Diseases and Sciences, 63*(8), 1997. doi:10.1007/s10620-018-5161-x	VI	Current background information on BE epidemiology, risk, and progression	BE is more common than thought but risk of progression is low. Still no gold standard for risk prediction but models are being used with fair performance.	Uses up-to-date references most within the past 5-10 years to discuss GERD and association with risk of BE; also discusses risk of progression to EAC; good for additional background

Levy, A. G., Scherer, A. M., Zikmund-Fisher, B. J., Larkin, K., Barnes, G. D., & Fagerlin, A. (2018). Prevalence of and factors associated with patient nondisclosure of medically relevant information to clinicians. *JAMA Network Open, 1*(7), e185293. doi:10.1001/jamanetworkopen.2018.5293	VI	Two national nonprobability samples recruited to study probability and factors leading to nondisclosure of medical information	Themes for nondisclosure include disagreement with provider; fear of judgement or how they are perceived by provider; information not important to care; concern about time constraints; not wanting info in EHR; not wanting to make a change; previous bad experience	Large study(n=4510) but convenience sampled and predominantly white; reveals that 81% and 61% of patients withhold information intentionally. Suggests that providers need to do more to elicit information and to improve communication.
Manchester, J., Gray-Miceli, D. L., Metcalf, J. A., Paolini, C. A., Napier, A. H., Coogle, C. L., & Owens, M. G. (2014). Facilitating Lewin's change model with collaborative evaluation in promoting evidence based practices of health professionals. *Evaluation and Program Planning, 47*, 82-90. doi:10.1016/j.evalprogplan.2014.08.007	V	Review of three EBP change projects and how they incorporated Lewin's Change Model in healthcare.	Focus of the review is the use of Lewin's Change model for the translation of research into practice. Reviews the three stages: unfreezing, movement, and refreezing and their applicability to EBP practice change from implementation through sustainability.	Provides exemplars of ways in which to incorporate Lewin into EBP and how each project managed the 3 steps of practice change.

Mariotto, A. B, Yabroff, K. R., Shao, Y., Feuer, E. J., & Brown, M. L. (2011). Projections of the cost of cancer care in the United States: 2010–2020. *Journal of the National Cancer Institute, 103*(2), 117–128. https://doi.org/10.1093/jnci/djq495	VI	Uses SEER data to project the cost from 2010-2020 of the 17 most prevalent cancers in the U.S.	Cost burden for esophageal cancer treatment and management was listed as $80,000-96,000 for the first year following diagnosis, $6500 for each additional year, and $104,000-156,000 for the final year of life with cost dependent on age at diagnosis.	The per diagnosis cost of esophageal cancer is more than $250 thousand for the first and last year of life combined if under 65 years of age, and $184 thousand if diagnosed at age 65 or older.
McCarthy, L., Su, X., Crown, N., Turple, J., Brown, T. E. R., Walsh, K., . . . Rochon, P. (2016). Medication reconciliation interventions in ambulatory care: A scoping review. *American Journal of Health-System Pharmacy, 73*(22), 1845-1857. doi:10.2146/ajhp150916	I	Scoping Lit review on med reconciliation in ambulatory care identified 15 studies looking at med reconciliation research to look at design, interventions, and outcomes	most outcomes based on improvement/completeness of med reconciliation; most studies used interviewing, medication vial review(brown-bagging), and med list review in some combination; history most often taken by nurse, MA, or pharmacist and reconciliation by provider, nurse or pharmacist; facilitators identified at patient, staff, and clinic levels	Many studies utilize clinical pharmacists which isn't feasible in most ambulatory care settings. Lack of info in any study on effectiveness of accuracy of med list in reducing harm; outcomes primarily focus on process improvement and accuracy of list; for purposes of QI project individual intervention studies may provide ideas for specific interventions not otherwise considered;

Melnyk, B. M., & Fineout-Overholt, E. (2019). *Evidence-based practice in nursing & healthcare: A guide to best practice* (Fourth ed.). Philadelphia: Wolters Kluwer.	V	Guideline that provides information on application of EBP into nursing practice.	Utilized for background information on method of evaluating levels of evidence	Used to aid determining level of evidence.
National Cancer Institute. (2020). Cancer trends progress report: Financial burden of cancer care. Retrieved from: https://progressreport.cancer.gov/after/economic_burden	VII	NCI looks at cancer trends and cost burden for cancers and lists aggregate costs of top 17 cancers in US.	Esophageal cancer the US ranks 16th in annual costs expended for cancer management. Cost has increased from more than $1.3 billion in 2010 to nearly $1.7 billion in 2018. Aggregate costs are separated by phase: $683 million for first year after diagnosis, $204 million for ongoing care, and $791 million in the last year of life.	Based on the 2018 data, the overall annual cost of care for all patients with esophageal cancer was approximately $1.7 billion. The annual cost can be broken down into phases of care with $683 million spent on initial care, $204 million for ongoing care, and $791 million for care during the last year of life. If early screening improves, these costs could be substantially reduced.

Noone, J., & Blanchette, C. M. (2018). The value of self-medication: Summary of existing evidence. *Journal of Medical Economics, 21*(2), 201-211. doi:10.1080/13696998.2017.1390473	VI	Targeted review of lit to determine economic value of self-care measured in access, time, productivity	Found that for conditions that were self-treatable w/OTC medications there was economic value to pts, payers, employers r/t cost savings and productivity; disadvantages include wrong self-diagnosis; potential for abuse/misuse; ADEs/interactions	Health literacy, access to care, and economics influence OTC medication choice among all adults; pt. feel that self-care is an essential to their health; preserves autonomy to manage common conditions, increase productivity, and reduce healthcare expenses; limitations include limited discussion on specific disease processes and broad discussion on global availability of OTC medications
Peery, A. F., Crockett, S. D., Barritt, A. S., Dellon, E. S., Eluri, S., Gangarosa, L. M., . . .Sandler, R. S. (2015). Burden of gastrointestinal, liver, and pancreatic diseases in the United States. *Gastroenterology, 149*(7), 1731-1741.e3.	VI	Report on burden of GI disease in the US looking at incidence and prevalence, costs to evaluate and treat; costs of ambulatory, emergent, and hospital care; cancer rates and death rates from disease	Useful background information on incidence and cost of esophageal symptoms, disease, and related cancers	Used to define problem background and purpose; data compiled and report completed by the American Gastroenterological Association

10.1053/j.gastro.2015.08.045				
Peery, A. F., Crockett, S. D., Murphy, C. C., Lund, J. L., Dellon, E. S., Williams, J. L., . . . Sandler, R. S. (2019). Burden and cost of gastrointestinal, liver, and pancreatic diseases in the United States: Update 2018. *Gastroenterology*, *156*(1), 254-272.e11. doi:10.1053/j.gastro.2018.08.063	VI	Review of burden and cost of GI disease in the US. This is an update to the 2015 report.	Noted data changes related to incidence of esophageal cancer and rates of death r/t esophageal cancer. Also cancer statistics now derived from CDC.	Updated project to reflect most current data on esophageal disease compiled by the AGA

Rey, E., Barceló, M., Zapardiel, J., Sobreviela, E., Muñoz, M., & Díaz-Rubio, M. (2014). Is the reflux disease questionnaire useful for identifying GERD according to the Montreal definition? *BMC Gastroenterology, 14*(1), 17-17. doi:10.1186/1471-230X-14-17	IV	Observational, cross-sectional multicenter study. Found sensitivity and specificity for GERD in pt. with reported troublesome symptoms 63.2/80.2% and for PPI users with ongoing symptoms sens/spec was 65.4/71.8% using a cut-off score of 3	Study looking at the validity of RDQ GERD tool to ID GERD based on the Montreal definition of reflux that causes troublesome symptoms or complications; was useful for those on and off PPIs; would be useful in primary care to establish a diagnosis of GERD by the Montreal def of troublesome symptoms.	RDQ is a 12 question tool, harder to find for use in QI project and longer than QerdQ. Strengths are large cohort (n=4574) with few exclusion criteria to allow full representation of population. Weaknesses - observational study, no correlation to 24-hour pH testing although other studies have validated in this manner.
Richter, J. E., & Rubenstein, J. H. (2018). Presentation and epidemiology of gastroesophageal reflux disease. *Gastroenterology, 154*(2), 267-276.	VI	Provides background on GERD including epidemiology worldwide, prevalence, trends, and demographic factors; reviews environmental risk and genetic risk	Thorough background on GERD epidemiology	Useful background information on GERD related to background of the problem
Rubenstein, J. H. & Thrift, A. P. (2015). Risk factors and populations at risk: Selection of patients for screening for Barrett's oesophagus. Best Practice & Research: Clinical *Gastroenterology,*	VI	Looks at individual and population risks for BE and compares the current models for BE risk assessment	No gold standard tool identified to assess risk for BE but dose note that the risk assessment tools used for BE perform better than the Gail Breast Cancer Risk assessment (for comparison).	Provides a good assessment and side-by-side comparison of risk assessment tools for BE; good background information on BE risk in populations

29(1), 41-50. doi:10.1016/j.bpg.2014.11.00				
Runge, T. M., Abrams, J. A., & Shaheen, N. J. (2015). Epidemiology of Barrett's esophagus and esophageal adenocarcinoma. *Gastroenterology Clinics of North America, 44*(2), 203.	VI	Overview of epidemiology of BE and EAC; breaks down odds of BE with individual risk factors; also looks at progression to EAC factors and discusses risk of progression	Good for background of risk factors and odds ratios for each	Used to discuss risk factors of progression and will be useful for education of providers when evaluating risk for BE in clinic
Sarzynski, E. M., Luz, C. C., Rios-Bedoya, C. F., & Zhou, S. (2014). Considerations for using the 'brown bag' strategy to reconcile medications during routine outpatient office visits. *Quality in Primary Care, 22*(4), 177.	VI	Cross-sectional pilot study; conducted in a geriatric clinic; 2 groups brown-baggers and non-brown baggers	Found that despite brown-bagging only 72% brought in medications and only 39% brought all meds. Only 35% med lists were complete; only 6.5% were accurate. Best results came from semi-structured interviewing w/brown-baggers, but was useful with both groups	Limitations: small study in singe office over 3-month period. Study found that OTC med documentation was better in brown-baggers; semi-structured interviewing provided best info on meds used among both groups.

Serper, M., McCarthy, D. M., Patzer, R. E., King, J. P., Bailey, S. C., Smith, S. G., . . . Wolf, M. S. (2013). What patients think doctors know: Beliefs about provider knowledge as barriers to safe medication use. *Patient Education and Counselling, 93*(2), 306-311. doi:10.1016/j.pec.2013.06.030	VI	Structured interviews conducted in 2 settings (academic medical center and FQHC) to examine patient beliefs about what providers know about their medication use; study also looked at provider conducted med reconciliation, med education, side effects	Patients believe that providers have knowledge of their entire medication regimen including OTCs; looking at female/male responses 89/92% think provider knows of all meds; 84/86% think they know about OTCs; 95/85% think they know about meds prescribed by other providers; 49/41% acknowledge telling about current OTCs; and 36/33% have reported taking supplements	Only study found looking at patient beliefs about what providers know about their medications; no subsequent studies identified; parts of study relied on pt. recollection of events. Study identified significant gaps in pt./provider perception of current medications. Suggests that improved open communication can improve safety and quality of care.
Shaheen, N. J., Falk, G. W., Iyer, P. G., Gerson, L. B., & American College of Gastroenterology. (2016). ACG clinical guideline: Diagnosis and management of Barrett's esophagus. *The American Journal of Gastroenterology, 111*(1), 30. doi:10.1038/ajg.2015.322	I	Clinical practice guidelines for BE management from the American College of Gastroenterology	Provides in-depth information on identification, management, and long-term treatment of BE	Used these guidelines in discussion d/t more current recommendations.

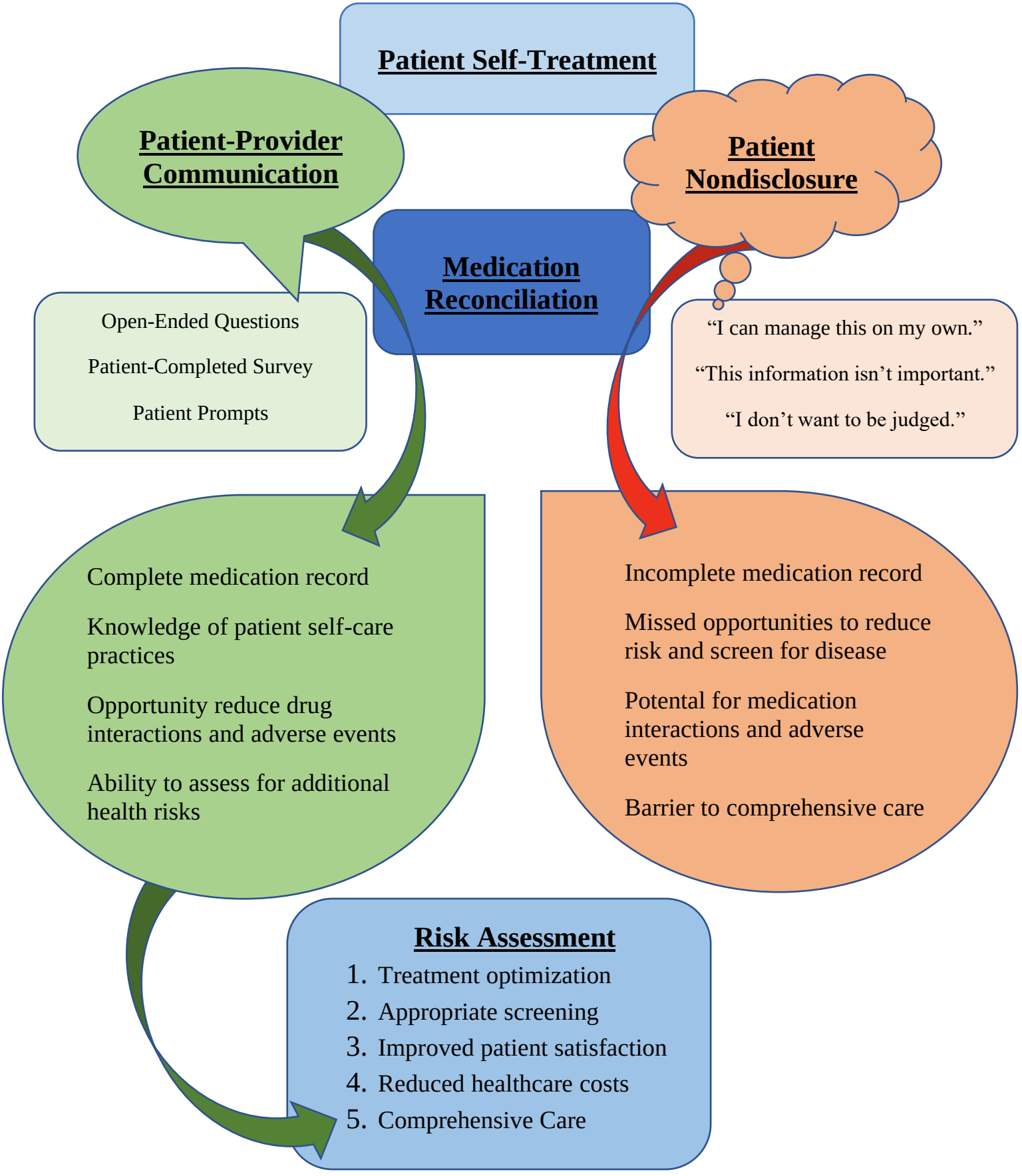
Spechler, S. J., Sharma, P., Souza, R. F., Inadomi, J. M., Shaheen, N. J., & American Gastroenterological Association. (2011). American Gastroenterological Association medical position statement on the management of Barrett's esophagus. *Gastroenterology, 140*(3), 1084-1091. doi:10.1053/j.gastro.2011.01.030	I	Position statement and practice guidelines for BE management from the American Gastroenterological Association	Provides in-depth information on identification, management, and long-term treatment of BE	Used to compare with guidelines from the ACG. Minor differences in screening guidelines. These are more liberal and would screen more people, perhaps unnecessarily
Uhl, M. C., Muth, C., Gerlach, F. M., Schoch, G., & Müller, B. S. (2018). Patient-perceived barriers and facilitators to the implementation of a medication review in primary care: A qualitative thematic analysis. *BMC Family Practice, 19*(1), 3-9. doi:10.1186/s12875-017-0707-0	VI	Qualitative study of 31 pts to determine barriers and facilitators to implementation of med reconciliation in primary care via pt. structured interview	Pts uniformly found med reconciliation to be necessary for quality care but barriers were identified regarding autonomy (did not want changes to meds/satisfied with current regimen; not wanting to disclose sensitive conditions; not wanting to justify OTC med use; not aware of possible interactions	Knowledge of barriers to obtaining full med list can provide better understanding of how to overcome them. Study conducted in Germany so may not be generalizable to US ambulatory care settings; notes that structured interviewing should include questions re: OTC meds and supplements because of frequency of omission

White, S., & Spruce, L. (2015). Perioperative nursing leaders implement clinical practice guidelines using the Iowa Model of Evidence-based Practice. *AORN Journal, 102*(1), 50-59. doi:10.1016/j.aorn.2015.04.001	VI	Exemplar of use of Iowa Model to implement practice change in perioperative setting to improve post-operative infection rates through EBP handwashing protocol.	Walks through each step of Iowa Model to implement EBP practice change.	Use as an exemplar on use of Iowa Model and importance of good implementation strategies to promote acceptance and sustainability of change.
Wolff, C. M., Nowacki, A. S., Yeh, J., & Hickner, J. M. (2014). A randomized controlled trial of two interventions to improve medication reconciliation. *Journal of the American Board of Family Medicine, 27*(3), 347-355. doi:10.3122/jabfm.2014.03.130240	II	RTC (n=440) 2 interventions to improve med reconciliation; 1) pt. reviews and updates printed med list 2) medication review w/open-ended questions; 4 groups: control, 2 individual intervention groups, both intervention group	20 different providers in 2 family health clinics; MA's initiated process and interviews, providers reconciled; Med rec added approx. 1.5 min to OV time; Only improvement over control group was in the both interventions group with 75.6% agreement in med list; multistep process of patient prompting and interviewing improves medication reconciliation	strengths: large number completed on adults 18+ so not limited to older adults; again shows that multistep intervention with prompting (med list) and interviewing provides best improvement

Zabaleta-del-Olmo, E., Bolibar, B., García-Ortíz, L., García-Campayo, J., Llobera, J., Bellón, J. Á., & Ramos, R. (2015). Building interventions in primary health care for long-term effectiveness in health promotion and disease prevention. A focus on complex and multi-risk interventions. *Preventive Medicine, 76,* S1-S4. doi:10.1016/j.ypmed.2015.03.011	VI	Discussion r/t incorporation of health promotion and disease prevention interventions into primary care and the effect of using complex interventions	Reviews the difficulty of implementation d/t time, workload, and lack of knowledge and skills; also acknowledges concern for implementing multiple changes directed at health promotion/disease prevention at once; conclude that higher risk of the population and intensity of the intervention, the more effective it is	May be useful article for implementation of project. Project implementation should consider barriers during design

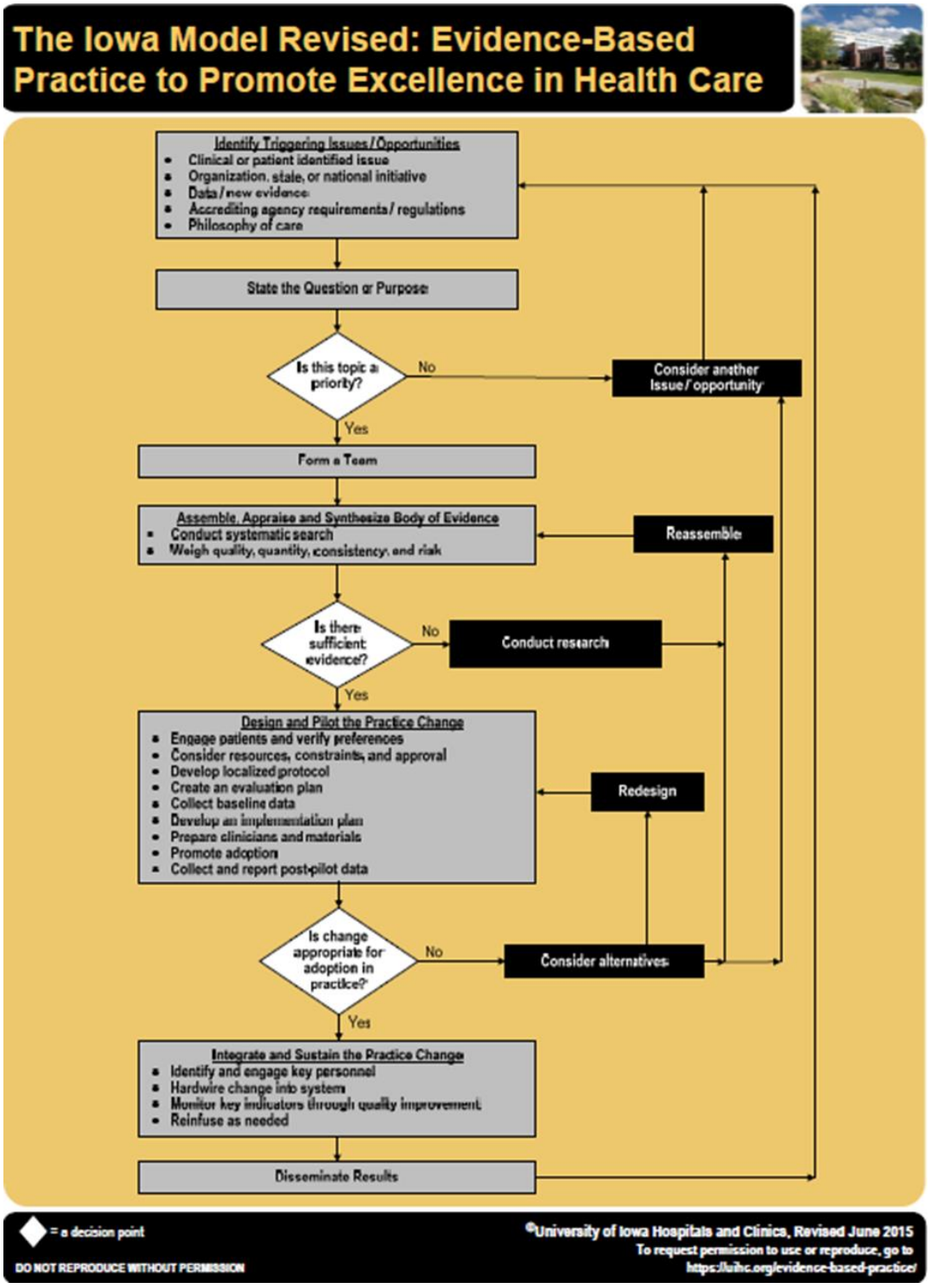
Appendix B

Concept Map



Appendix C

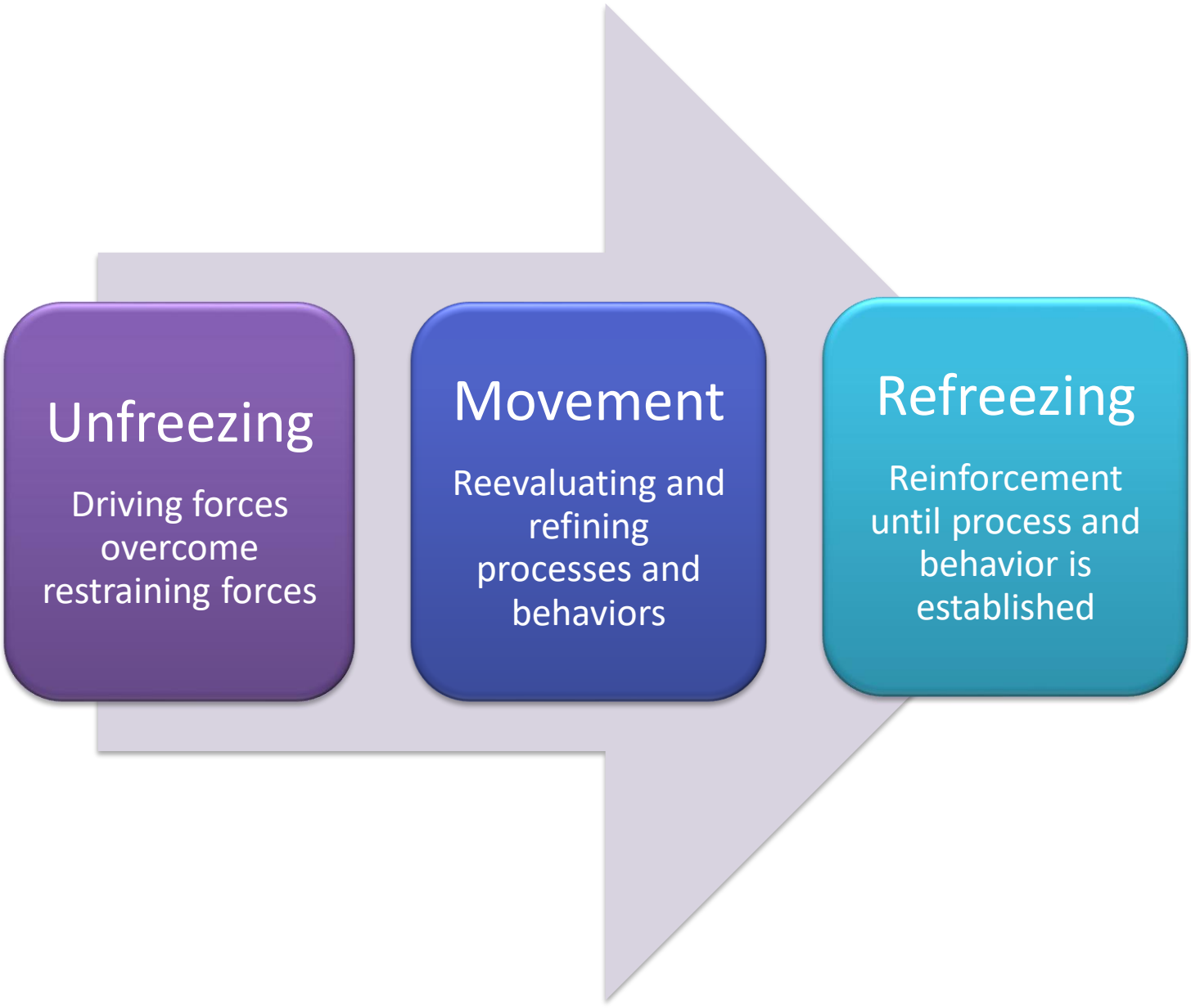
Iowa Model Revised



(Iowa Model Collaborative, 2017).

Appendix D

Lewin's Change Model



Appendix E
Letter of Support from Project Site

[redacted]

Durham NC, 27707
Phone: 919-419-0242
Fax: 919-401-4172

April 4th, 2019

To East Carolina University College of Nursing:

We at [redacted] have reviewed Virginia Ashley's DNP Project Proposal "Identifying Barrett's Esophagus Risk in a Primary Care Setting". Ms. Ashley has organizational support and approval to conduct this project within our institution. We understand that the timeframe for this project is from the date of this letter through April 30, 2020. Implementation at the project site will occur August/September through November 30, 2019, unless otherwise negotiated. We understand that for Ms. Ashley to achieve completion of the DNP program, dissemination of the project will be required by the University which will include a public presentation related to the project and a manuscript submission will be encouraged.

Our organization has deemed this project as a quality improvement initiative that may guide policy development regarding screening for risk. Our organization is aware that this project will be processed through the University and Medical Center Internal Review Board of East Carolina University (UMCIRB). Our organization does not have an Internal Review Board (IRB).

Thank you,

[redacted]

Kate Kulenic, FNP-BC

Appendix F

QI Project Budget

Barrett's Esophagus Risk Project Budget

Item	Cost	Quantity	Total
Supplies			
Staples 20 lb. copy paper - 8-ream case	$ 37.45	1	$ 37.45
HP Black toner cartridge for HP LaserJet Pro	$ 166.92	1	$ 166.92
Lunch and Learn			
Assorted Sandwich Tray	$ 45.00	1	$ 45.00
Large Salad	$ 15.00	1	$ 15.00
Tea - 1 Gallon	$ 5.00	2	$ 10.00
Two Week Follow-up Breakfast Meeting			
Bagels and Muffins	$ 30.00	1	$ 30.00
Coffee	$ 15.00	1	$ 15.00
Wrap-up/Results Lunch Meeting			
Assorted Wraps	$ 35.00	1	$ 35.00
Large Salad	$ 15.00	1	$ 15.00
Cookie Tray	$ 15.00	1	$ 15.00
Tea - 1 Gallon	$ 5.00	2	$ 10.00
Travel - Round Trip $0.58/mile (as of Jan. 1, 2019)			
64 miles/trip	$ 37.12	10	$ 371.20
			$ 765.57

Appendix G

QI Project Self-certification Tool

Quality Improvement/Program Evaluation Self-Certification Tool

Purpose:

Projects that do not meet the federal definition of human research pursuant to 45 CFR 46 do not require IRB review. This tool was developed to assist in the determination of when a project falls outside of the IRB's purview.

Instructions:

Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. The IRB will not review your responses as part of the self-certification process.

Name of Project Leader:

Virginia Ashley

Project Title:

Identifying Barrett's Esophagus Risk in a Primary Care Setting

Brief description of Project/Goals:

This QI project, implemented in the Fall of 2019 in a 3-provider, urban family practice, will identify adults who are at high risk for developing Barrett's esophagus (BE), the pre-cancerous lesion for esophageal adenocarcinoma. An over-the-counter (OTC) medication survey will be used to identify patients who are self-treating. Patients identified as taking antiacids and antireflux medications or who have a history of gastroesophageal reflux disease (GERD) will complete the validated GerdQ questionnaire to evaluate the frequency and severity of GERD symptoms. The OTC medication survey and GerdQ questionnaire are patient-completed tools which will be offered to all new and routine follow-up patients age 18 years and older. During the office visit the provider will identify symptomatic GERD based on the GerdQ results. The presence of GERD symptoms will prompt evaluation of the level of BE risk, GERD treatment optimization, and assessment for the need for BE screening.

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

- ○ Yes
- ● No

Has the project received funding (e.g. federal, industry) to be conducted as a human subject research study?

- ○ Yes
- ● No

Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- ○ Yes
- ● No

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?

- ○ Yes
- ● No

Will the results of the project be published, presented or disseminated outside of the institution or program conducting it?

- ○ Yes
- ● No

Based on your responses, the project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings. Finally, if the project changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project. 6/25/2019

Appendix H

DNP Project Post-visit Survey and Data Collection Tool

Provider Post-visit Survey

1. Based on the **OTC medication survey** did you identify a **new problem** to be addressed now or at a future visit?
   Yes No
2. Based on the **OTC medication survey** did you make a **change to the treatment plan**: education, medication, testing, other treatment, referral?
   Yes No
3. Based on the **GerdQ results** did you identify previously **unknown or under-treated GERD?**
   Yes No
4. Is this patient at **increased risk for Barrett's esophagus** based on the **BE risk assessment**?
   Yes No
5. If at **risk for BE**, based on your clinical assessment, how do you **plan to manage**? Circle all that apply.

Monitor/Continue Current Regimen Lifestyle Mods Optimize GERD meds Refer to GI Refer for EGD

Data Collection Tool

BE Risk QI Project Data Collection Tool

	# Pts/ # Forms	# GerdQ Completed	# New GERD Dx	# BE High Risk	Q1 Yes	Q2 Yes	Q3 Yes	Q4 Yes	Q5 No Change	Q5 Modify Tx	Q5 Referral	GERD, male, 2 other RF
Week 1	Project Educational Seminar											
Week 2	Started data collection											
Week 3	14	13	0	0	1	3	0	0				
Week 4												
Week 5												
Week 6	17	16	3	1	5	5	3	1		1		2
Week 7												
Week 8	9	8	4	1	2	3	4	1		2		1
Week 9												
Week 10	16	16	4	2	4	4	4	2			2	3
Week 11												
Week 12	15	15	3	1	4	3	3	1		1	1	2
Week 13												
Week 14												
Week 15	11	11	2	0	2	2	2	2			1	1
	82	79	16	5	18	20	16	7		4	4	9

Appendix I

Over-the-counter Medication Survey

List **over-the-counter medications** taken **since your last visit. Circle how often** you take them.

1. **Pain/headache (include oral and topical medicines):**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

2. **Cough/Cold:**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

3. **Sinus/Allergies (include nasal sprays, inhalers, and oral medicines):**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

4. **Sleep aids:**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

5. **Topical Ointment/Cream/Lotion/Shampoo/Eye or Ear Drops**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

6. **Diarrhea/Constipation (include suppositories, enemas, and oral medicines):**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

7. **Gas/Bloating:**
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

8. **Heartburn/Indigestion/Reflux: *******
   Name/Dose_____

Never/Rarely-----Monthly---------Several times/month------Weekly-------Several times/week-------Daily or more often

*******Please complete the GerdQ assessment on the back of this page if you take any over the counter or prescription medications for heartburn, indigestion, or reflux symptoms.**

Appendix J

AstraZeneca License Agreement for the GerdQ Tool

Licence Agreement for Gastroesophageal Reflux Disease Questionnaire (GerdQ)

This Licence Agreement (the "**Agreement**") is made effective as of the last date written below (the "**Effective Date**") by and between

(1) ASTRAZENECA AB, a company incorporated in Sweden under no. 556011-7482 with offices at SE-431 83 Mölndal, Sweden ("**AstraZeneca**"); and

(2) Virginia Ashley, of East Carolina University College of Nursing a university incorporated in the United States with offices at Health Services Building, Greenville, NC 27858-4353 ("**Licensee**").

Recitals

(A) WHEREAS, AstraZeneca is in the possession of a certain questionnaire known as the Gastroesophageal Reflux Disease Questionnaire (the "GerdQ").

(B) WHEREAS, Licensee wishes to obtain, and AstraZeneca is willing to grant to Licensee, a right to use the GerdQ solely for the Study (as defined below) on the terms and conditions set forth below.

(C) WHEREAS, Licensee wishes to administer the GerdQ via paper

(D) NOW THEREFORE, the parties agree as follows.

Agreement

1 Licence

1.1 Upon payment of the Licence Fee and for the duration of the Term (as defined below), AstraZeneca grants to Licensee and its affiliates a non-exclusive, non-assignable and non-sublicenseable licence (the "**Licence**") to:

(a) use the as the GerdQ worldwide in the language(s) set out in Section 1.3 below and in such other languages as agreed between the parties in writing from time to time during the Term, which shall include permission for use (to the extent necessary for the conduct of the Study) by contract research organisations and eCOA vendors engaged by the Licensee and/or its affiliate(s) to conduct the Study;

(b) arrange for any other reasonably required translations and validations of the as the GerdQ be made through RWS Life Sciences, done in accordance with the process defined by AstraZeneca, as notified by RWS Life Sciences to the Licensee;

(c) submit copies of the as GerdQ and background materials (including, without limitation, documentation relating to its development, and supporting instructions and algorithms) (Associated Materials) to the relevant regulatory authorities worldwide for evaluation and scientific advice on as the GerdQ at any time prior to,

during or after the Study, as well as to use such Associated Materials for Licensee's own evaluation and review of as the GerdQ for use in the Study. If there are documents that AstraZeneca does not wish to share directly with the Licensee, AstraZeneca will submit these directly to the regulatory authorities; and

(d) keep copies of any Associated Materials and completed copies of as the GerdQ, together with any other relevant materials (including, without limitation, software and validation materials), and to share the same with its affiliates, contract research organisations, regulatory authorities, ethics committees and other third parties for the purposes of review and analysis of the Study data (including, without limitation, maximising Study validity and ensuring the validity of the interpretation of the Study results), archival purposes and regulatory purposes;

solely in connection with the Licensee's study, entitled Quality Improvement project set in one primary care clinic in NC to assess GERD symptom frequency and severity in patients self-treating with OTC medications. (the "**Study**").

1.2 Licensee shall not modify, publish, disclose or distribute the GerdQ or part thereof or otherwise use the GerdQ or part thereof for any other purpose than as set forth in Section 1.1. All uses by Licensee under the Licence shall be in compliance with all applicable laws, rules and regulations.

1.3 Where Licensee submits or shares copies of the GerdQ and/or the Associated Materials with third parties as set forth in Section 1.1, Licensee shall make such recipients aware that the GerdQ and/or the Associated Materials are: (i) owned by AstraZeneca and used by the Licensee under licensing arrangements with AstraZeneca and (ii) to be used solely in connection with the Study.

1.4 RWS Life Sciences shall, upon receipt of the Licence Fee, provide Licensee with one electronic copy in PDF format or similar of the GerdQ in the following language:

English (USA)
Spanish (USA)

together with electronic copies in PDF format or similar of AstraZeneca's scoring instructions and the Associated Materials, all of which will be sent by e-mail to the Licensee following the Effective Date at an e-mail address provided to AstraZeneca by the Licensee in writing.

2 Licence Fee

2.1 Commercial Use: Licensee shall pay to RWS Life Sciences a fee (the "Licence Fee") in the amount of two-thousand and five hundred United States dollars ($2,500.00 US) for each language version of the GerdQ to be provided as per Section 1.3 and as agreed between the parties in writing from time to time during the Term. There will also be a per-study three hundred and fifty United States dollars ($350) handling fee. If hard copies of the license agreement or translations are requested, an additional shipping fee (which shall be agreed between the parties prior to shipping) will apply. The Licence Fee shall be invoiced by RWS Life Sciences to Licensee at the address set forth in the preamble of this Agreement and be paid by Licensee within thirty (30) days following RWS Life Sciences' issuance of such invoice.

Total license fee to be paid for study is: $0 (waived for non-commercial use)

2.2 The parties agree that, unless otherwise agreed between the parties in writing in advance, the Licence Fee and per study handling fee will remain the same for any other languages the parties agree the of the GerdQ shall be used in for the Study within a period of 5 years starting at the Effective Date.

2.3 Non-Commercial Use: No licence fee for hospital and university or non-industry-sponsored use.

3 Intellectual Property

3.1 AstraZeneca warrants that it is the sole legal and beneficial owner of, and owns all rights and interests in the of the GerdQ and Associated Materials and that the use of the of the GerdQ and Associated Materials by Licensee and its affiliates shall not infringe any third party rights.

3.2 Subject to the Licence, all intellectual property rights, including copyrights and all other rights in and to the of the GerdQ shall be and remain at all times the exclusive property of AstraZeneca. All data collected through the permitted use by Licensee of the of the GerdQ shall be and remain at all times the exclusive property of Licensee and/or its affiliates.

4 Term and Termination

4.1 This Agreement shall become effective on the Effective Date and shall continue in force until the completion of the Study (at which time this Agreement shall terminate automatically without further notice), unless earlier terminated in accordance with this Section 4.1 (the "**Term**"). Either party may terminate this Agreement immediately by giving written notice to the other party if the other party should commit a material breach of any of its obligations under this Agreement and fail to rectify such breach within thirty (30) days after having been given a written request for such rectification.

4.2 Sections 1.2 and 3 and this Section 4.2 shall survive the termination of this Agreement.

5 Miscellaneous

5.1 The interpretation and construction of this Agreement shall be governed by the laws of Sweden excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

5.2 The parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the Swedish courts for any action, suit or proceeding arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding related thereto except in such courts.

THIS AGREEMENT IS EXECUTED by authorised representatives of the parties.

Place: East Hartford, Connecticut, USA

Date: May 28, 2019

Name (Print): Marybeth Madigan

RWS LIFE SCIENCES ON BEHALF OF:
ASTRAZENECA AB (PUBL)

[redacted]

Place: Greenville, North Carolina, USA

Date: 5-28-2019

Name (Print): Virginia Ashley

East Carolina University College of Nursing

[redacted]

Appendix K

GerdQ Tool – English

GerdQ

Questionnaire for patients with upper gastrointestinal symptoms

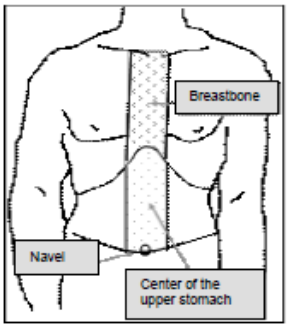
Please answer each question by ticking one box per row.

Thinking about your symptoms over the past 7 days

	Never	1 day	2-3 days	4-7 days
1. How often did you have a burning feeling behind your breastbone (heartburn)?	☐	☐	☐	☐
2. How often did you have stomach contents (liquid or food) moving upwards to your throat or mouth (regurgitation)?	☐	☐	☐	☐
3. How often did you have a pain in the center of the upper stomach?	☐	☐	☐	☐
4. How often did you have nausea?	☐	☐	☐	☐
5. How often did you have difficulty getting a good night's sleep because of your heartburn and/or regurgitation?	☐	☐	☐	☐
6. How often did you take additional medication for your heartburn and/or regurgitation other than what the physician told you to take? (such as Tums, Rolaids, Maalox?)	☐	☐	☐	☐

Total Score_____/ Impact Score_____

8+ 2+



For Provider Use Only:

BE Risk Evaluation: Circle All that apply

GERD

Male

Caucasian

Age 50+

Smoker (former or current)

↑ WHR

Family Hx BE/EAC

Total Circled: _____

BE High Risk

Male
GERD + 2

Female
GERD + 4

Appendix L

GerdQ Tool – Spanish

GerdQ

Cuestionario para pacientes con síntomas gastrointestinales superiores

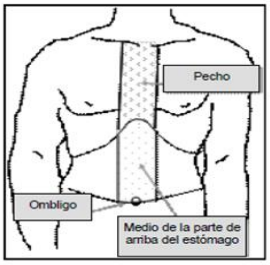
Por favor conteste cada pregunta marcando **una** casilla en cada línea.

Pensando en sus síntomas durante los últimos 7 días

	Nunca	1 día	2-3 días	4-7 días
1. ¿Con qué frecuencia tuvo una sensación de ardor o acidez en el pecho?	☐	☐	☐	☐
2. ¿Con qué frecuencia se le subió el contenido del estómago (líquido o comida) a la garganta o la boca (reflujo)?	☐	☐	☐	☐
3. ¿Con qué frecuencia tuvo dolor en el medio de la parte de arriba del estómago (abdomen)?	☐	☐	☐	☐
4. ¿Con qué frecuencia tuvo náusea?	☐	☐	☐	☐
5. ¿Con qué frecuencia tuvo dificultad para dormir bien por la noche a causa del ardor o la acidez (reflujo)?	☐	☐	☐	☐
6. ¿Con qué frecuencia tomó medicina adicional para el ardor o la acidez (reflujo) aparte de la que el médico le dijo que tomara? ¿(tales como Tums, Rolaids, Maalox)?	☐	☐	☐	☐

Total Score_____/ Impact Score_____

(8+) (2+)



For Provider Use Only:

BE Risk Evaluation: Circle All that apply

GERD

Male

Caucasian

Age 50+

Smoker (former or current)

↑ WHR

Family Hx BE/EAC

Total Circled: _____

BE High Risk

Male
GERD + 2

Female
GERD + 4

Appendix M

GerdQ Scoring Instructions

GerdQ items

GerdQ consists of 6 items, 4 of which are positive predictors of GERD and 2 are negative predictors of GERD.

1. Positive predictors for GERD: Heartburn (HB), regurgitation (R), sleep disturbances due to HB and/or R and use of OTC medications in addition to prescription medicines due to HB and/or R.

   These 4 items each score from 0-3, where 0=no day, 1=1 day, 2=2-3 days and 3=4-7 days of the individual item during the previous week.

2. Negative predictors for GERD: Epigastric pain and nausea

   These 2 items score from 3-0, ie in reverse order to the positive predictors, where 0=4-7 days, 1=2-3 days, 2=1 day and 3=no day of the individual item during the previous week.

   The sum score of these 6 items therefore range between 0-18.

GerdQ cut off score (GerdQ score sum: 8 or above) for the diagnosis of GERD

Based on the definition of GERD applied in the Diamond Study (presence of macroscopic esophagitis (LA grades A-D) and/or pathological esophageal pH (pH below 4 for at least 5.5% of the 24 hours), the presence of GERD was plotted by GerdQ sum score. This showed that the prevalence of GERD increases with increasing GerdQ sum score as expected. In the Diamond study population (primary care), no one had GERD in the sum score interval 0-2. In the 3-7 sum score interval, 52% had GERD and ***81% of those with a sum score of 8 or above had GERD***. Of those with a sum score of 11 or higher, 87% had GERD.

Applying a sum score of 8 of above therefore provides high accuracy for the GERD diagnosis.

Approx. 20% of those with a sum score higher that 8 do not have GERD (false positives). Likewise a sum score of 0-2 excludes GERD with high accuracy (predominantly dyspepsia). The intermediate group, with a sum score of 3-7, diagnostic accuracy is low for GERD (approx 50%; ie "toss of a coin accuracy"). However, half of those in this sum score interval have GERD (false negatives) that cannot be identified with acceptable accuracy. This represents 1/3 of those with GERD in the Diamond population. Thus, GerdQ was able to capture 2 of 3 GERD patients with high accuracy in the Diamond population (primary care patients with upper gastrointestinal symptoms).

This GerdQ cut-off definition for the diagnosis of GERD is applicable to **untreated** patients. Undiagnosed patients on treatment with a PPI, would likely score lower in the GerdQ due to an anticipated positive treatment response. Thus, a disproportionate proportion of well treated patients would be expected to have a sum score below 8, and could thus be false negatives for a GERD diagnosis.
NB! The total GerdQ sum score (0-18) is only used for the diagnosis of GERD.

Assessment of GERD impact

Previous studies have shown that mild-severe reflux symptoms lead to significant reduction of health-related quality of life as do reflux symptoms occurring at least weekly (Wiklund et al 2006; Aro et al 2003).

The GERD Impact Scale (GIS), which was included in the Diamond study, includes four questions as markers of the impact of reflux symptoms/GERD on daily life. The two GIS questions included in the GerdQ (sleep disturbances due to heartburn/regurgitation and consumption of OTC medications in addition to Rx medications for such symptoms (eg antacids) showed to be good and accurate indicators of how GERD impacts daily life. They are also positive predictors of a GERD diagnosis. The sum score of these two disease impact questions range from 0-6, with 0 meaning no impact on daily life and 6 maximal impact on daily life.

The sum score of these two impact questions in GerdQ, shows close positive correlation with the total GerdQ sum score, and a sum score of these two questions of:

- 1 or above captures 89%
- 2 or above captures 66%
- **3 or above captures 42%**
- 4 or above captures 22%

of those with a GerdQ score of 8 or more (GERD) and identifies those that are most impacted. Thus, a sum score of 3 or above identifies the half of the GERD population that is most impacted by their disease.

Cut off scores for treatment response

RDQ has previously been shown to be a sensitive tool to measure treatment response to PPIs. The Diamond study showed that GerdQ has a similar high responsiveness as the GERD dimension in RDQ.

In the GerdQ, the four positive predictors for GERD are used (heartburn, regurgitation, reflux-related sleep disturbances and use of OTC medication due to reflux symptoms) for this measurement.

In GERD trials, the primary end-point for positive response to treatment with aPPI has typically been "complete resolution of heartburn" or "not more than mild heartburn on at most one day the last week of treatment". This end-point combines severity and frequency. The GerdQ only scores frequency as frequency and severity are typically closely related.

Applying this clinical trial end-point definition and extending it to include also the other characteristic GERD symptom, regurgitation, leads to the following definition of positive response to treatment in GerdQ

***"Not more than one day of heartburn and /or regurgitation the last week of treatment"*, which corresponds to a score of 0-1 for heartburn and/or regurgitation and any score of 2 or 3 of any of these items indicates residual GERD symptoms/problems and suggests treatment alteration.**

The two impact questions, ie sleep disturbances and OTC medication, due to heartburn and/or regurgitation, can also be scored and assessed in a similar way as they frequently occur in GERD patients.

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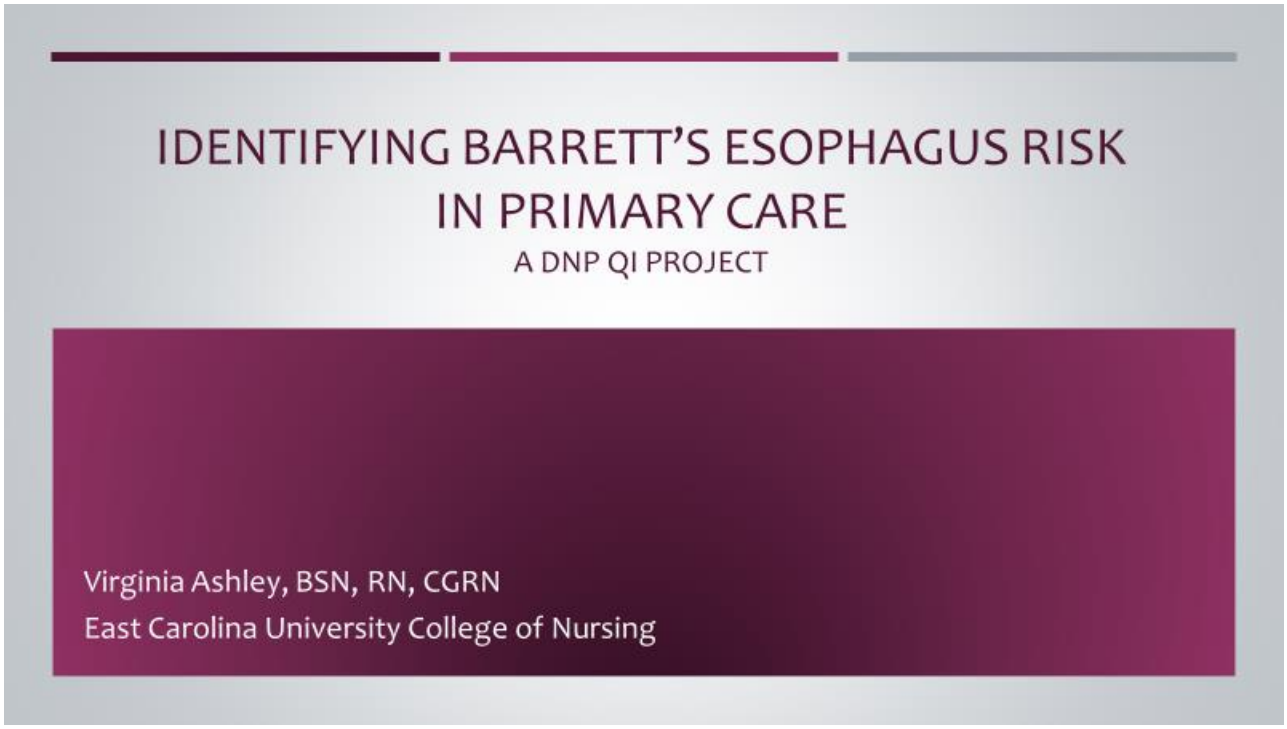
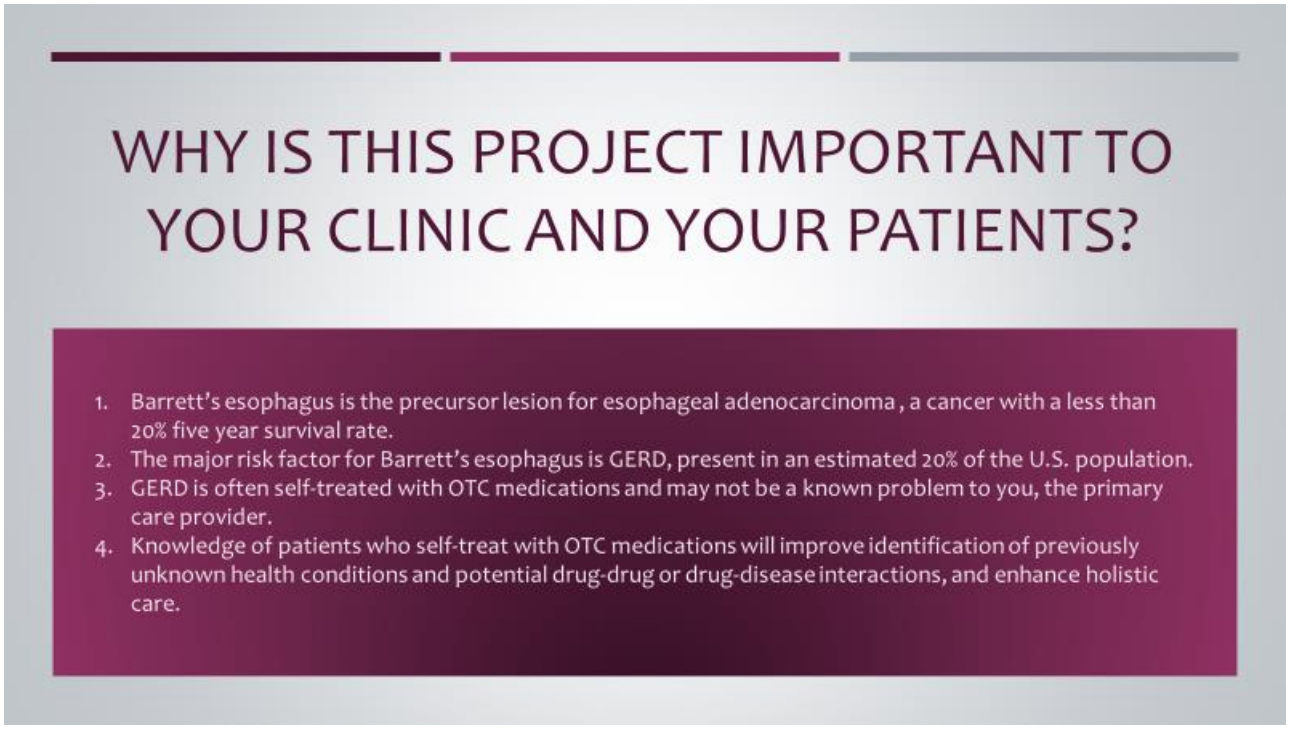
Appendix N

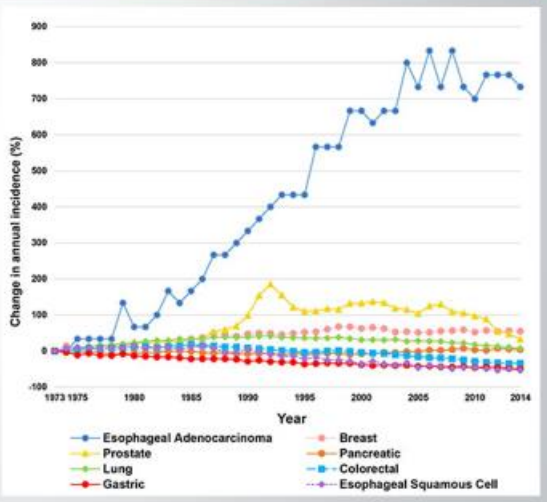
Educational PowerPoint Presentation





WHY IS IDENTIFYING BARRETT'S ESOPHAGUS RISK IN PRIMARY CARE IMPORTANT?

- Barrett's esophagus is the only precursor lesion for esophageal adenocarcinoma
  - <20% 5-year survival rate
  - >60% of esophageal cancer found at stage III or IV
  - 7-fold increase in EAC incidence over past 40 years
- There is no cost-effective screening method for use in general population (yet)
  - Cytosponge
  - Genetic and biologic markers
- Early identification and treatment will prevent progression to cancer
- Barrett's esophagus is asymptomatic; EAC becomes symptomatic as cancer progresses



(Hang, et al., 2018)

GERD-ESOPHAGEAL CANCER RELATIONSHIP

Gastroesophageal Reflux

- Reflux and regurgitation
- Erosive Esophagitis
- Chronic acid exposure leads to changes in the normal squamous epithelium

- **20% of adults**

Barrett's Esophagus

- Columnar epithelium replaces squamous epithelium
- Metaplasia
- Dysplasia
  - Low Grade
  - High Grade

- **10-15% risk if GERD present, 1-2% risk in general population**

Esophageal Adenocarcinoma

- 7-fold increase in incidence over past 40 years
- <20% 5-year survival rate
- Often asymptomatic until late stage
- 90% of EAC diagnoses in patients with no BE diagnosis

- **0.5% BE patients will develop EAC annually**

(Shaheen, Falk, Iyer, & Gerson, 2016)

HOW DO WE IDENTIFY BE RISK IN PRIMARY CARE?

- **Identify the patient who is self-treating with over-the-counter acid reducers**
  - Patient-completed OTC medication survey for adult primary care patients (18 yrs or older)
    - Focus on new primary care adult patients and annual physicals, return patients as time allows
  - PPIs, H2RAs, and traditional antacids are easily accessible
  - Patients are less likely to discuss their OTC medications unless prompted
- **Complete GerdQ tool**
  - Any patient with GERD history, upper GI symptoms, or taking acid-reducing medicines
  - Validated evaluation method for GERD and its impact in primary care
- **Evaluate for risk factors of Barrett's esophagus**
  - GERD, Caucasian, male, >50 yrs old, central obesity (WHR > 0.9), smoking, family history of BE or EAC

OTC MEDICATION USE

- 81% of U.S. adults choose OTC medications as their first line of treatment for minor symptoms
- 35% - 47% of older adults use OTC medications regularly
- Self-care is essential to consumer health
  - Empowers autonomy
  - Increases productivity
  - Reduces healthcare expenses
  - Important to preventative health
- Self-treatment may increase patient risk
  - Providers may be uniformed about patient self-medication
  - Increased risk of adverse drug events
  - Some OTC medications can exacerbate health conditions

(Noone & Blanchette, 2018; Albert et al., 2014)

Why don't patients disclose OTC medication use?

- Fear of judgement
- Embarrassment
- Don't want to take providers time
- Don't think OTC medications matter
- Don't feel provider can help with their problem

(Levy et al., 2018)

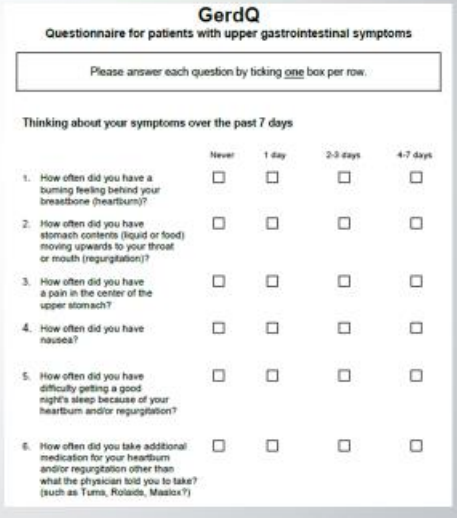
OTC MEDICATION SURVEY

- Reviews 8 broad groups of OTC medications
- Gradual implementation of full survey
- Begins with 3 categories of GI medications
  - Diarrhea/Constipation
  - Gas/Bloating meds
  - Heartburn/Indigestion/Reflux
- Others will be added as impact to clinic flow is assessed
  - Pain/Headache meds
  - Sleep aids
  - Cough/Cold
  - Sinus/Allergy
  - Topical Ointment/Cream/Lotion/Shampoo/Eye or Ear drops
- OTC medications reconciled in EMR per clinic policy

GERDQ ASSESSMENT TOOL

- Should be completed by patients:
  - With upper GI symptoms
  - Taking OTC or prescription antacids
  - With a diagnosis of GERD
- Validated 6-item tool for symptom assessment and impact
- Provides ability to presumptively diagnosis GERD in primary care setting
- Sensitivity of 65%; Specificity 71% for GERD
  - Total score 8 or more
- Impact score (last 2 questions)
  - 3 or more is positive correlation to GERD disease impact

(Jones, et al., 2009)



GerdQ

Questionnaire for patients with upper gastrointestinal symptoms

Please answer each question by ticking one box per row.

Thinking about your symptoms over the past 7 days

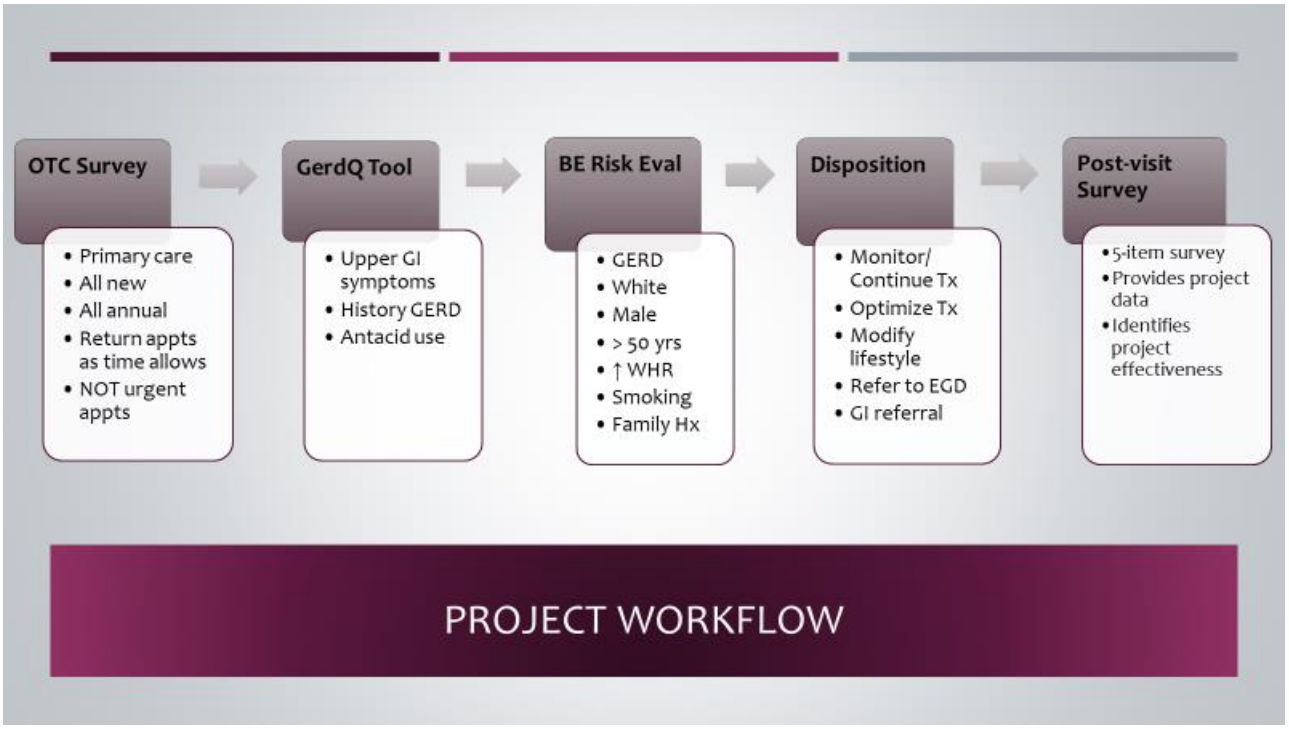
	Never	1 day	2-3 days	4-7 days
1. How often did you have a burning feeling behind your breastbone (heartburn)?	☐	☐	☐	☐
2. How often did you have stomach contents (liquid or food) moving upwards to your throat or mouth (regurgitation)?	☐	☐	☐	☐
3. How often did you have a pain in the center of the upper stomach?	☐	☐	☐	☐
4. How often did you have nausea?	☐	☐	☐	☐
5. How often did you have difficulty getting a good night's sleep because of your heartburn and/or regurgitation?	☐	☐	☐	☐
6. How often did you take additional medication for your heartburn and/or regurgitation other than what the physician told you to take? (such as Tums, Rolaids, Maalox?)	☐	☐	☐	☐

POST-VISIT PROVIDER SURVEY

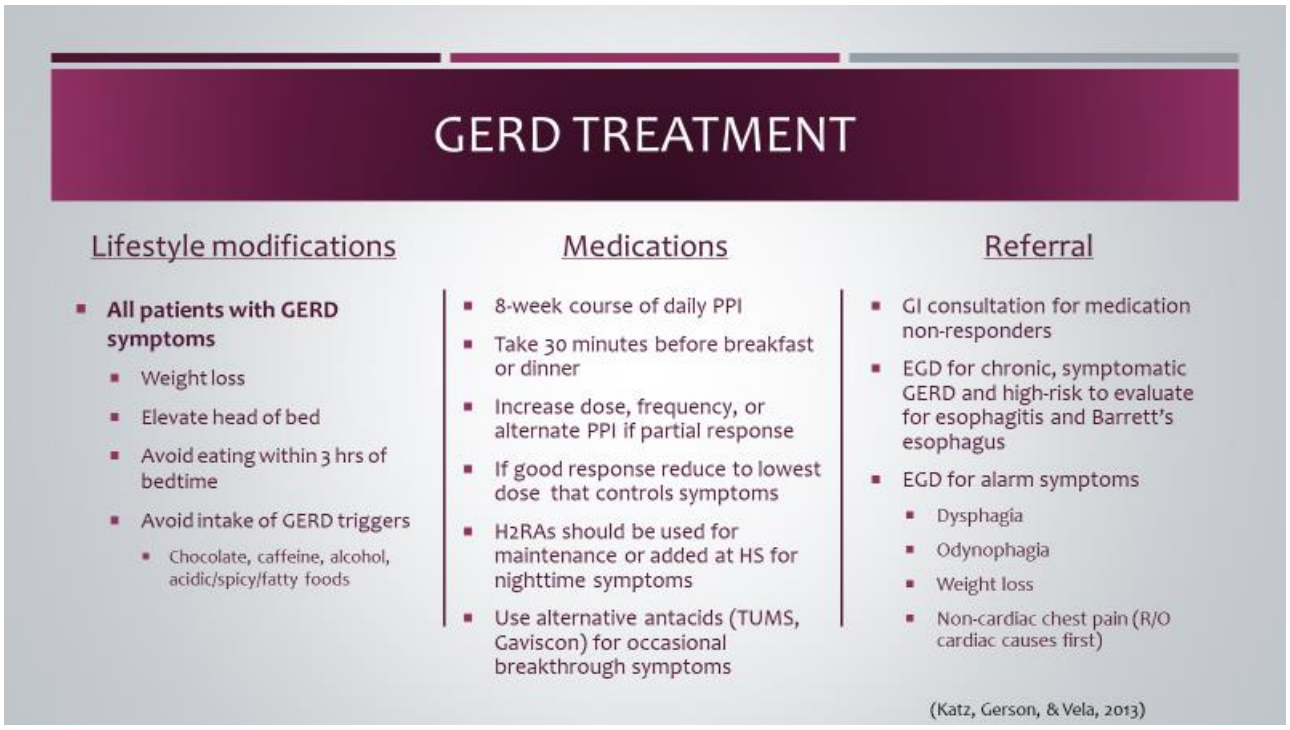
- 5-item survey
- Looks at project impact on patient care
- Will provide the primary data for this DNP QI project
- Should be completed post-visit on any patient completing the OTC medication survey/GerdQ tool
- Questions 1-4: circle Yes or No
- Question 5: Circle all that apply
- Area for any notes that you might want to include

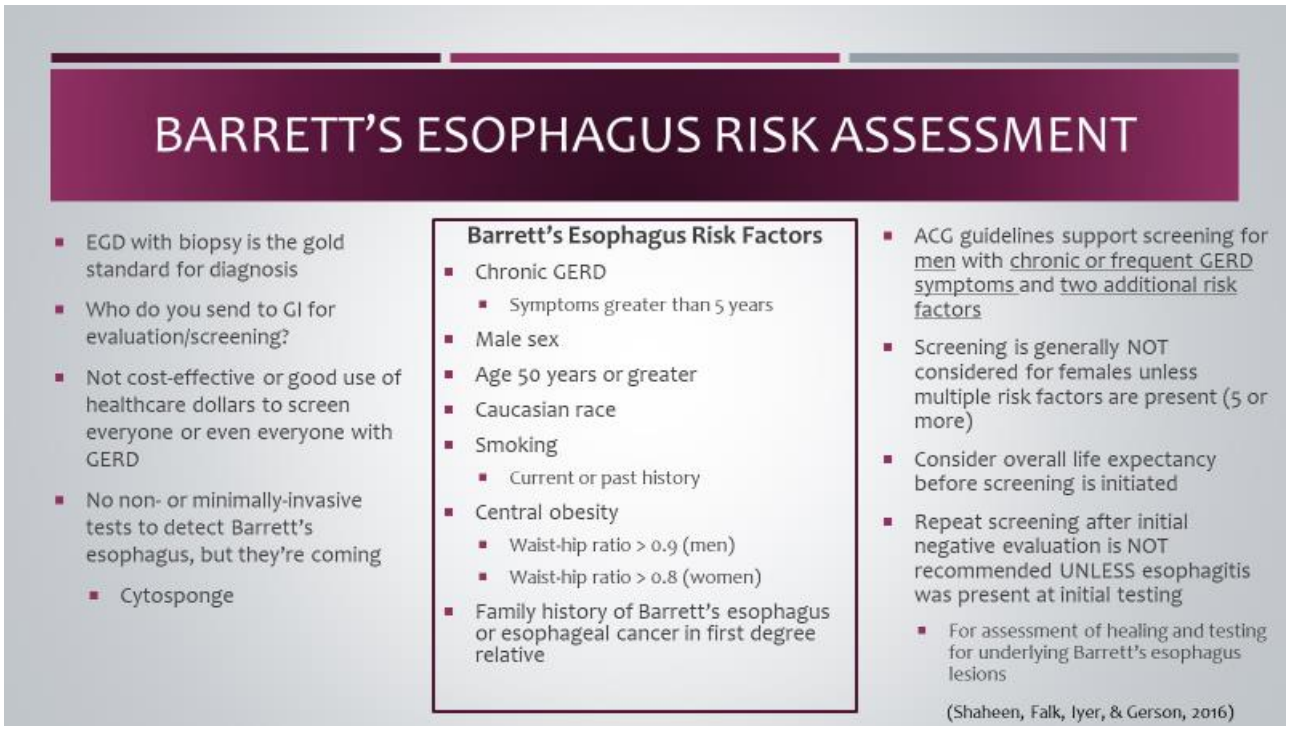
1. Based on the **OTC medication survey** did you identify a **new problem** to be addressed now or at a future visit?
   Yes No
2. Based on the **OTC medication survey** did you make a **change to the treatment plan**: education, medication, testing, other treatment, referral?
   Yes No
3. Based on the **GerdQ results** did you identify previously **unknown or under-treated GERD?**
   Yes No
4. Is this patient at **increased risk for Barrett's esophagus** based on the **BE risk assessment**?
   Yes No
5. If at **risk for BE**, based on your clinical assessment, how do you **plan to manage**? Circle all that apply.

Monitor/Continue Current Regimen Lifestyle Mods Optimize GERD meds Refer to GI Refer for EGD



PROJECT WORKFLOW


GERD TREATMENT
Lifestyle modifications
All patients with GERD symptoms
Weight loss
Elevate head of bed
Avoid eating within 3 hrs of bedtime
Avoid intake of GERD triggers
Chocolate, caffeine, alcohol, acidic/spicy/fatty foods
Medications
8-week course of daily PPI
Take 30 minutes before breakfast or dinner
Increase dose, frequency, or alternate PPI if partial response
If good response reduce to lowest dose that controls symptoms
H2RAs should be used for maintenance or added at HS for nighttime symptoms
Use alternative antacids (TUMS, Gaviscon) for occasional breakthrough symptoms
Referral
GI consultation for medication non-responders
EGD for chronic, symptomatic GERD and high-risk to evaluate for esophagitis and Barrett's esophagus
EGD for alarm symptoms
Dysphagia
Odynophagia
Weight loss
Non-cardiac chest pain (R/O cardiac causes first)
(Katz, Gerson, & Vela, 2013)


BARRETT'S ESOPHAGUS RISK ASSESSMENT
EGD with biopsy is the gold standard for diagnosis
Who do you send to GI for evaluation/screening?
Not cost-effective or good use of healthcare dollars to screen everyone or even everyone with GERD
No non- or minimally-invasive tests to detect Barrett's esophagus, but they're coming
Cytosponge
Barrett's Esophagus Risk Factors
Chronic GERD
Symptoms greater than 5 years
Male sex
Age 50 years or greater
Caucasian race
Smoking
Current or past history
Central obesity
Waist-hip ratio > 0.9 (men)
Waist-hip ratio > 0.8 (women)
Family history of Barrett's esophagus or esophageal cancer in first degree relative
ACG guidelines support screening for men with chronic or frequent GERD symptoms and two additional risk factors
Screening is generally NOT considered for females unless multiple risk factors are present (5 or more)
Consider overall life expectancy before screening is initiated
Repeat screening after initial negative evaluation is NOT recommended UNLESS esophagitis was present at initial testing
For assessment of healing and testing for underlying Barrett's esophagus lesions
(Shaheen, Falk, Iyer, & Gerson, 2016)

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