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Addressing Inappropriate Proton Pump Inhibitor Use in Gastro-esophageal Reflux

Disease to Decrease Adverse Outcomes:

A Case Report

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Abstract

This paper reviews a clinical case report that warrants the use of proton-pump inhibitors (PPIs), according to current guidelines. It examines the cost benefit of this treatment and evaluates adverse outcomes associated with both short and long-term PPI use through a compilation of literature review. It further examines ways to minimize inappropriate PPI use, including minimizing dosages, utilizing lifestyle factors, step down therapy, intermittent therapy, and on-demand therapy according to guidelines. Review of the importance of reevaluating PPI use in the primary care setting, especially amongst older adults as described in the clinical case, is discussed. Implementation of these recommendations for addressing inappropriate PPI use in primary care will likely decrease the risks of adverse outcomes.

Keywords: Gastro-esophageal Reflux Disease, Proton Pump Inhibitors, Step-Down Therapy, Intermittent Therapy, On-Demand Therapy, Adverse Outcomes, Guidelines

Independent Study

Background

An elderly female presents to the clinic with symptoms associated with gastro-esophageal reflux disease (GERD), which warrants empiric treatment according to current guidelines with proton pump inhibitors (PPIs). She is otherwise healthy with her only chronic medical condition being hypertension. After prescribing omeprazole 20mg to be taken daily, she is instructed to follow-up in the clinic at which time reevaluation of her symptoms will take place. In anticipatory case management for this patient, the provider questions whether or not to continue the PPI at the follow-up appointment.

This paper addresses this question by examining appropriate proton-pump inhibitor use and its risk-benefit analysis for patients in the primary care setting with GERD. Although current guidelines recommend PPI use due to their high efficacy in treatment of GERD, they also suggest limiting this treatment to eight weeks as initial therapy (Katz, Lauren, & Marcelo, 2013; Iwakiri, Kinoshita, Habu, et al., 2016). Despite this recommendation, few clinicians follow these guidelines, and PPI prescriptions continue to rise with most being repeat scripts for long-term therapy (Haastrup, Paulsen, Begtrup, Hansen, et al., 2014; Heidelbaugh, Kim, Chang, & Walker, 2012). In addition, it is estimated that 25% to 70% of people are inappropriately prescribed a PPI (Boghossian, Rahid, Thompson, Welch, et al., 2017). Literature has also suggested that proton pump inhibitors, which were initially viewed to have little to no adverse effects, are not as safe as originally thought. PPI use has been associated with enteric infections, pneumonia, bone fractures, nutrient malabsorption, chronic kidney disease, and dementia (Walsh, Kwan, Marr, et al., 2016; Wilsdon, Hendrix, Thynne, et al., 2017). Some of these

conditions have been shown to gain increased risk with higher dosages and/or longer terms of therapy (Freedberg, Kim, & Yang, 2017; Harrison, 2016). Yet, given the risks and common overutilization of proton-pump inhibitors, providers still often neglect to reevaluate patients at follow-up appointments for the need of PPIs for symptom management.

The purpose of this paper is to examine ways to minimize inappropriate PPI use in the primary care setting in order to decrease the chance of adverse outcomes. Evaluation of de-prescribing, step-down therapy, minimizing dosages and treatment lengths, and alternative lifestyle factors are evaluated as options for effectively treating GERD symptoms. Managing GERD with these options are anticipated to minimize overutilization and inappropriate use while decreasing unwarranted effects of proton pump inhibitors.

Case Report

History

E.L, an 88-year-old female, presented to her primary care provider (PCP) with a chief complaint of a “cough that won’t go away.” She was treated for bronchitis about two months prior to her visit at a separate facility, which was around the same time that her symptoms began. She describes her cough as “irritating” with sensation “in the middle” of her chest. Her cough is present daily, worse at night, and associated with a “sour taste” in her mouth, a sore throat, and a “burning” in her chest. She denies production or hemoptysis. She has tried a humidifier, cough syrup, and “inhalers” thus far with no symptom relief. She denies any exposure to anyone who has been sick.

When asked about similar symptomology in the past, E.L denies having anything

comparable to her presentation at this appointment. Further investigation does reveal a history of “heartburn” for which she takes Tums. She also mentions drinking “a pot of coffee” every morning and frequently eating after eight p.m. prior to going to bed in the evening. E.L is not particularly concerned about the severity of this cough; however, she is slightly bothered with its interruption of sleep.

E.L’s past medical history includes hypertension, which is controlled with lisinopril 10mg once daily by mouth. E.L states she has been on this medication “for years” and has had no issues with it since its start. She is up-to-date on current immunizations, including seasonal influenza. Patient is unaware of any family history regarding gastro-esophageal reflux disease (GERD), although she does mention a history of heart disease, diabetes, and colon cancer in various first and second-degree relatives.

E.L’s social history includes a ½ pack a day history of cigarette use “for many years” with cessation of all tobacco products “about ten years ago.” Alcohol consumption reveals “occasional use, maybe 1-2 beers a night.” She denies any illicit drug use. She is a retired female who lives locally with her adult daughter. E.L’s full history of presenting illness, review of systems and pertinent negatives can be found in her Electronic Medical Record (EMR) as outlined in Appendix A.

Exam and Diagnostics

The physical examination reveals vital signs within normal limits with mental status and orientation intact. Head, eyes, ears, nose, throat, and neck assessments are all unremarkable. Skin is warm, dry, and intact throughout with no rashes apparent. Lungs are clear with respirations of regular rate and rhythm. Cough noted in middle of the chest appears dry in nature. Heart is of regular rate and rhythm, peripheral pulses are +2

throughout, and no lower extremity edema noted. Abdominal exam reveals a soft, non-tender abdomen with bowel sounds throughout. There is no organomegaly noted. A chest x-ray obtained with this visit is unremarkable. Details of physical exam are listed in Appendix A.

Treatment and Follow Up

E.L is diagnosed with gastro-esophageal reflux disease and is prescribed omeprazole 20mg to be taken once daily. Her PCP provides additional education in the appropriateness of taking this prescription along with a thorough discussion of adverse side effects. E.L is also provided with a list of lifestyle changes to include diet, exercise and weight loss, elevation of the head of her bed, and avoidance of food consumption close to bedtime. She is instructed to return to the clinic in eight weeks for follow-up and further discussion of her GERD.

Literature Review

The key to all medication prescriptions is to ensure that the benefits of the medication outweigh the costs. Each medication added to a patient's regimen, however, already increases risks associated with its own side effects and many times, polypharmacy. In the clinical case presented above, this is exactly the situation at hand as E.L begins to extend her medication list to include the appropriately prescribed PPI for her treatment of GERD. The addition of this medication for an eighty-eight year old female not only increases the risk of drug-to-drug interactions but also heightens risk factors for medical conditions that she may already be prone to getting (Scarpignato, Gatta, Zullo, & Blandizzi, 2016). For this reason, evaluation of the appropriateness of this

prescription begins by reviewing both long and short-term adverse outcomes associated with proton-pump inhibitor use.

Adverse Outcomes

Short-term adverse outcomes with proton pump inhibitors include side effects, such as diarrhea, abdominal pain, headache, and constipation (Scholl, Dellon, & Shaheen, 2011). These complaints are typically short-lived and are often relieved by decreasing PPI dose or discontinuing. Drug-to-drug interactions are also common with PPI use (Scarpignato, et al., 2016). These interactions may be especially true in the case of omeprazole due to its action on CYP3A4 and CYP2C19. Again, this expected finding could easily be relieved with discontinuation of the medication and avoidance of polypharmacy.

Less common, but of more concern, are the increased risks of enteric infections, such as *Clostridium difficile* and community-acquired pneumonia associated with PPI exposure (Heidelbaugh, Kim, Chang, & Walker, 2012). These adverse outcomes may be of greater concern in elderly patients, such as the case described above, due to their age and the dangers associated in this population with morbidity and mortality.

Unfortunately, short-term adverse outcomes are not the only concern as research shows that the majority of patients prescribed a PPI will stay on a PPI (Scarpignato, et al., 2016). Inappropriate long-term PPI use is even more common in the elderly. This type of drug therapy is associated with increased risks of dementia, bone fractures, mineral and vitamin malabsorption, and chronic kidney disease. Given the seriousness of many of these conditions, further examinations of these adverse events as they relate to the clinical case are discussed.

Dementia. A study examining the PPI associated risk of dementia revealed that the likelihood of developing dementia is 44% higher amongst PPI users compared to non-users (Freedberg, et al., 2017). Participants who occasionally used PPIs had a 16% increase of dementia development. This association can also be related to increased Alzheimer's risk. According to statistics derived from the Center of Disease Control, in 2014 Alzheimer's was listed as the third leading cause of death amongst individuals over the age of 85 (Heron, 2016). Given E.L's age, this adverse outcome must be taken into consideration when discussing possible long-term therapy.

Bone Fractures. In addition to increased mortality risk associated with dementia, women over the age of 65 who incur a hip fracture are also at an increased risk of death within the following year. A meta-analysis of eighteen studies revealed that PPIs are associated with a modestly increased risk of fractures (Zhou, Huang, Li, Sun, et al., 2016). Hip fractures, in particular, were increased in both short and long term PPI use, although one study showed increased rates with higher dosages and longer time frames (Heidelbaugh, 2013). Given that hip fractures in elderly women significantly increase morbidity and mortality within the following year, this is something to be mindful of in appropriate follow-up. E.L is already at an increased risk due to her history of smoking, her given age and her need for a walker with ambulation.

Mineral and vitamin malabsorption. Although several studies debate which vitamins and minerals are affected with PPI use and the significance, two areas in particular are of concern for E.L. First, calcium absorption is thought to contribute to the increased risk of fractures as previously mentioned (Zhou, et al., 2016). Yet, review of calcium supplementation of those taking PPIs did not show any significance to suggest

adding it into current guidelines. The same was true regarding evaluation of vitamin B12, of which a deficiency is thought to affect upwards of 20% of the elderly population already (Heidelbaugh, 2013). In fact, PPI use was associated with a 2-4 times increase of vitamin B12 deficiency, and further risk association with this medication occurred with increased age (Freedberg, et al., 2017; Heidelbaugh, et al., 2012). Many elderly already exhibit contributing factors to several nutritional deficiencies with E.L being no exception.

Chronic Kidney Disease. Medical and social history to include long-standing tobacco use and hypertension are primary contributing factors to developing chronic kidney disease (CKD). E.L's family history of heart disease may also suggest an increased risk. In addition, new studies are now evaluating the effect that PPIs may also have on this condition. A recent report published in Medscape (2016), suggests that PPIs contribute to elevated serum creatinine, increased glomerular filtration rates (GFR), and ultimately CKD when compared to H2-blocker use or no antacid use (Harrison, 2016). In other words, E.L's new prescription may also increase her associated risk factors for CKD.

Although literature reviewed may differ in the degree to which PPIs contribute to the adverse outcomes as stated above, many researchers agree that additional interventions do not result in any benefit (Freedberg, et al., 2017). Furthermore, all literature concurred that the best way to avoid adverse outcomes is to follow associated guidelines and minimize inappropriate PPI use.

Minimizing Inappropriate PPI Use

Research shows that adhering to guidelines is one of the safest and most rational ways to utilize PPIs, minimizing adverse effects (Scarpignato, et al., 2016). E.L. is appropriately prescribed once daily omeprazole 20mg, aligning with current guidelines published with the American College of Gastroenterology (Katz, Gerson, & Vela, 2013). However, if her PCP fails to trial her off of this PPI at her eight-week follow-up, she will become one of the 25% to 70% of people that are inappropriately prescribed a PPI (Boghossian, Rahid, Thompson, Welch, et al., 2017). If there is no longer an indication for E.L. to be taking a PPI, then she is only exposed to the risk factors and will have no benefit.

Guidelines. Following guidelines will help to avoid inappropriate use of PPIs and, in turn, decrease adverse effects. Many guidelines agree that initial therapy of GERD should be a PPI, but they also suggest completing a trial off the medications after eight weeks (Katz, Gerson, & Vela, 2013). If symptoms return, guidelines suggest reinstating PPIs at the lowest dose possible or consider alternative therapy. To prevent adverse outcomes, guidelines suggest that providers consider step down therapy, utilizing H2blockers, alternating the timing of medication and implementing lifestyle factors (Katz, Gerson, & Vela, 2013). All of these recommendations help to decrease overutilization and unwarranted effects of PPI use. Full details of GERD guidelines can be found in Appendix B.

Short-term. Several strategies that align with current guidelines can be used to address associated adverse outcomes with short-term PPI use. Often, these strategies

begin with ensuring the patient is utilizing the minimal dosage necessary and taking medications as intended in combination with alleviating lifestyle factors.

To address these points, often education is needed for both the patient and provider in regards to short-term therapy. Providers should be reminded to follow guidelines that suggest the minimal dosage for all PPI users (Katz, Gerson, & Vela, 2013). To avoid increasing the dose, providers should ensure that the patients are taking these medications appropriately. It may be that patients are not taking the medications at appropriate times or not as intended, which could be dampening the PPI effectiveness. Evaluation of polypharmacy should also occur to ensure that it is not another reason the medications are not being effective.

Addressing lifestyle factors that may alleviate symptoms is also suggested for all PPI users. Research recommends avoiding common dietary triggers individualized for the patient and/or known to increase stomach PH (Katz, Gerson, & Vela, 2013). Exercise and weight loss may also be of benefit; one study demonstrated that 54% of overweight/obese subjects who lost weight were able to come off of PPI therapy and that 32% more were able to cut their dosage in half (Scarpignato, et al., 2016). In other words, adding lifestyle management may prevent the need for longer therapy and/or increased dosages short term.

Long-term. To decrease the risk of adverse outcomes associated with long-term use, the provider must first evaluate the appropriateness of the prescription (Katz, Gerson, & Vela, 2013). Unfortunately, re-evaluation of PPI use is not always done as we note the debate of the provider in the case study being evaluated. In fact, in one study nearly half of PPI users stated they were never asked in follow-up about their upper GI

symptoms; therefore, never had an opportunity to discuss stepping down or coming off from therapy (Heidelbaugh, et al., 2012). Additionally, providers see patients staying on PPIs simply because they were not educated as to when to stop therapy during initial prescription. As little as 1 in 10 PPI users are educated on when to discontinue PPI use from their providers (Haastrup, Paulsen, Begtrup, Hansen, & Jarbøl, 2014). It is clear that the very first intervention necessary to prevent inappropriate PPI use is to ensure that PCPs are providing education and re-evaluation. Providing E.L with additional anticipatory guidance at this initial visit may help to address this concern.

If long-term use is deemed necessary, secondary interventions are aimed at those similar to prevention of short-term effects. Reducing these adversaries can be done through dosage deduction and education as discussed earlier. If patient has never been trialed at a lower dosage, research suggests cutting the standard dose of PPI in half to see if symptoms remain in control (Walsh, Kwan, Marr, Papoushek, & Lyon, 2016). Often symptoms remain in control at this lower dosage. In one study of long-term PPI users, thirty to fifty percent of participants remained symptom free on reduced dosages at three months after prescription change (Haastrup, et al., 2014). These results included participants with associated GERD risk factors similar to E.L's to include smoking, alcohol intake, and increased BMI.

In addition to dosage reduction, step down therapy, intermittent use, or on-demand therapy are also suggested as interventions, according to guidelines (Katz, Gerson, & Vela, 2013). These strategies include stepping down therapy to H2 blockers or minimal PPI use, utilizing intermittent treatments, according to symptoms and/or taking PPIs only when symptoms arise or "on-demand." Despite the fact that many patients are

satisfied with on these types of therapy, few clinicians actually utilize them (Freedberg, Kim, & Yang, 2017; Heidelbaugh, 2013). In regards to step-down treatment, one study revealed that only 58.5% of patients currently on a PPI had ever tried H2 blockers for symptom relief (Walsh, et al., 2016). Still, implications for such therapies are clear as the result is decreased exposure to PPI use and thus decreased risk for adverse outcomes.

If re-evaluation of patients prescribed PPIs does not reveal an appropriate long-term reason as suggested by guidelines in Appendix B, then the next step is to de-prescribe. In the management of mild to moderate GERD, up to 64% of individuals were able to successfully come off of their PPIs (Haastrup, et al., 2014). In literature examining de-prescribing of PPIs, consensus shows that tapering seems to be the best method tolerated amongst patients. There still remains debate, however, on the best way to achieve this result.

Challenges to Minimizing PPI Use

Despite the strong evidence suggesting minimizing inappropriate PPI use, still challenges exist out in practice to appropriately do so. One of them may be that PCPs often lack the time and knowledge to intervene (Walsh, et al., 2016). With acute clinical visits, if a patient's medication list includes PPIs with GERD symptom relief, oftentimes it is viewed as the medication working and, therefore, seen as no need to address. In addition, a common challenge with PPI use in particular includes its availability for over-the-counter use. In this case, the provider may not even be aware that their patient has been utilizing PPIs.

Another challenge includes additional adverse effects associated with the abrupt stopping of PPIs: hypergastrinemia and rebound acid hypersecretion (Hasstrup et al.,

2014). These conditions after long-term PPI use may cause severe dyspeptic symptoms, sometimes worse than those experienced prior to initiation of PPI therapy (Niv, 2011). To combat this challenge, some literature suggests that utilizing a tapering approach may help to alleviate these discomforts (Haastrup, et al., 2014; Niv, 2011). As mentioned previously however, no present research has guidelines of how to complete tapering of PPIs.

Conclusion

After reviewing possible adverse effects of PPI use, it is evident that minimizing inappropriate PPI therapy is crucial in the primary care setting. Reevaluating the need for long-term PPI therapy for E.L's treatment of GERD symptoms and trial off therapy is strongly warranted in this clinical case study. Guidelines associated with GERD treatment agree, and adhering to these guidelines is the safest way to utilize this class of medication. Yet, providers still question this practice and often neglect to de-prescribe or minimize PPI use, and the result is an inappropriately prescribed medication for symptoms that the patient may not be having. In the case of E.L, an otherwise healthy elderly female, there is no need to increase the risk of medical conditions commonly associated with increased morbidity and mortality in this population. The clinician's better choice is to use alternatives as recommended to decrease the need for PPI use and thus decrease any risk for adverse events.

Learning Points

- PPIs are often inappropriately prescribed. Adhering to guidelines is the best and safest way to ensure PPIs are being utilized appropriately to avoid adverse outcomes.

- Proton-pump inhibitors are associated with serious adverse effects for both short and long-term use. If patients are inappropriately utilizing PPIs, they are only being exposed to the risk factors with no benefits.
- Education to patients on appropriate PPI use including anticipatory guidance, correct administration, and additional lifestyle factors may help to minimize adverse events and inappropriate PPI use.
- Education to providers is crucial to ensure appropriate PPI therapy. This education should include suggestions for evaluation of all patients currently on PPIs for de-prescribing, follow-up for new PPI users, and use of step-down, intermittent and on-demand therapy options.

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Appendix A

Electronic Medical Record for E.L.

Name: E.L **Age:** 88 **Date/Time of Encounter:** 3/10/2017

Gender: Female **Race:** Caucasian **Contact Information:** XXXXXX

Source of Information: Patient is primary source of information and considered a reliable resource.

History

Chief Concern: Cough that won't go away. Treated for bronchitis about two months ago.

History of Present Illness: EL presents to clinic with a primary complaint of a cough. Patient states that the cough began about "2-3 months ago" and that she does not recall any triggers at that onset. She states the cough sits in the middle of her chest and is sometimes associated with a "sour taste" in her mouth. She denies any production with this cough, although she does mention a "burning" sensation at times. She describes the overall characteristics as "irritating" more than anything. She mentions that the cough has been there daily since its onset but specifically is worse at night. She denies any exposure to anyone who has been sick in association with this complaint. She has tried a humidifier to help with symptom relief as well as some "cough syrup and inhalers" prescribed at another facility for possible bronchitis. She notes that none of these treatments have helped at this time. She denies any drainage from eyes, ears or nasal passages. She does mention a sore throat associated with this complaint.

Patient denies having similar symptoms as stated above in the past, although when asked about reflux, she does mention a history of "heartburn" for which she takes Tums. She also mentions drinking "a pot of coffee" every morning and frequently eating after 8pm prior to going to bed in the evening. EL is not particularly concerned about the severity of this cough interfering with her daily activities; however, she mentions it being more bothersome with interruption of sleep. She denies chest pain or shortness of breath. She denies any other complaints at this time.

Past Medical History:

1. Hypertension

Immunizations- Up to date, seasonal flu shot obtained

Family History: Patient is unsure if there is any history of gastroesophageal disease or upper GI disorders. She does mention a family history of heart disease, diabetes and colon cancer in first and second-degree relatives, although specifics on who are not disclosed.

Home Medications:

1. Lisinopril 10mg PO daily for hypertension
2. Tums, 2 tablets as needed for heartburn relief

Allergies: No known allergies to drugs, environment, or food

Social History: Elderly retired female who lives with daughter in town. She currently denies any tobacco products although she mentions that she did quit using cigarettes about “10 years ago.” She mentions occasionally having 1-2 beers a night and denies any other illicit drug use.

Review of Systems

Constitutional: Patient denies generalized weakness, fatigue, or fever.

Mental Health: No changes in social life factors, mood, memory, or sleep. Patient does note occasionally waking up from cough and “sour taste” in mouth at night.

Skin, Hair, Nails: Denies any skin changes associated with acute illness.

HEENT: Denies frequent headaches, swollen glands or lymph nodes. Denies visual or hearing changes, patient does have visual aids. Denies drainage or pain from eyes, ears, nose, and throat. Does mention sore throat and “sour taste” in mouth associated with cough as described in HPI.

Endocrine: No thyroid conditions or diabetic concerns

Chest & Lungs: No shortness of breath at rest. Patient denies increased work of breathing or wheezing. Positive for cough as described in HPI. No hemoptysis.

Cardiovascular: No chest pain or palpitations. No swelling in lower extremities, calf tenderness, or warmth.

Gastrointestinal: Denies nausea, vomiting, constipation, diarrhea, or complaints of pain.

Physical Examination **Vitals:** BP 130/80, Pulse 76, RR 16, Temp. 97.8

General Appearance: Patient is a well-developed, well-groomed, white female appearing her stated age of 88. She presents with calm demeanor, no signs of acute distress, sitting in exam room dressed appropriately. She cooperates throughout exam.

Mental Status: Alert and orientated X4, with appropriate thoughts and mood. Responds appropriately throughout exam with no signs of depression or anxiety.

Skin, Hair, Nails: Skin warm, dry and intact with appropriate color for race throughout

body. No abrasions, rashes or contusions noted.

HEENT: Head is midline and normocephalic without facial or scalp tenderness. Jugular venous distension not observed. **Eyes:** Pupils equal, round, reactive to light and accommodation. **Ears:** Auricles symmetrical, no nodules noted. Otoscopic findings indicate scant amount of cerumen in ears, no drainage or lesions. TMs pearly gray with visible cone of light and bony landmarks. No redness or effusion present. **Nose:** External nose midline with nares patent. No discharge noted. **Mouth & Throat:** Lips and oral cavity intact with moist, pink mucosa. **Neck:** Neck supple, no cervical lymphadenopathy noted. Thyroid midline with no nodules noted.

Chest & Lungs: Respirations of regular rate and rhythm without labor. Lungs sounds clear, no adventitious lung sounds present upon auscultation. Auscultation during patient cough appears dry.

Cardiovascular: Heart rate of regular rate and rhythm with S1, S2 auscultated; no murmurs present. Peripheral pulses equal, +2 bilaterally, no edema in lower extremities. Capillary refill of <2seconds.

Abdomen: Abdomen soft, round, nontender. Bowel sounds present and normoactive in all four quadrants. Negative for bruits. No CVA tenderness. No organomegaly.

Musculoskeletal: Patient able to get on and off examination table with minimal assistance. Gait is slow and shuffled, utilizing a walker for assistance.

Radiology: Chest Xray completed is unremarkable.

Assessment:

1. K21 Gastro-esophageal reflux disease

Plan:

1. Omeprazole 20mg prescribed and sent to the pharmacy of her choice. Instructed patient to stop taking the Tums at this time and to begin the omeprazole once daily starting today. Educated patient on adverse effects and all questions addressed.
2. Discussed lifestyle factors contributing to condition. Included recommendations on diet, exercise and weight loss as tolerated. Educated on elevating head of bed or increasing amount of pillows. Also discussed avoidance of trigger foods such as caffeine, alcohol, citrus fruits, spicy foods or anything else that she notices contributes to her personal symptom onset. Patient is also encouraged to eat earlier in the evening prior to bedtime.
3. Patient is instructed to return to clinic in 8 weeks for follow-up regarding her GERD or sooner if symptoms do not improve or get worse.

Information electronically recorded and signed by: Kimberly Williams, RN BSN, FNP Student

Appendix B

Table 1

Management of GERD

1. Weight loss is recommended for GERD patients who are overweight or have had recent weight gain. (Conditional recommendation, moderate level of evidence)

2. Head of bed elevation and avoidance of meals 2–3 h before bedtime should be recommended for patients with nocturnal GERD. (Conditional recommendation, low level of evidence)

3. Routine global elimination of food that can trigger reflux (including chocolate, caffeine, alcohol, acidic and/or spicy foods) is not recommended in the treatment of GERD. (Conditional recommendation, low level of evidence)

4. An 8-week course of PPIs is the therapy of choice for symptom relief and healing of erosive esophagitis. There are no major differences in efficacy between the different PPIs. (Strong recommendation, high level of evidence)

5. Traditional delayed release PPIs should be administered 30–60 min before meal for maximal pH control. (Strong recommendation, moderate level of evidence). Newer PPIs may offer dosing flexibility relative to meal timing. (Conditional recommendation, moderate level of evidence)

6. PPI therapy should be initiated at once a day dosing, before the first meal of the day. (Strong recommendation, moderate level of evidence). For patients with partial response to once daily therapy, tailored therapy with adjustment of dose timing and/or twice daily dosing should be considered in patients with night-time symptoms, variable schedules, and/or sleep disturbance. (Strong recommendation, low level of evidence).

7. Non-responders to PPI should be referred for evaluation. (Conditional recommendation, low level of evidence, see refractory GERD section).

8. In patients with partial response to PPI therapy, increasing the dose to twice daily therapy or

switching to a different PPI may provide additional symptom relief. (Conditional recommendation, low level evidence).

9. Maintenance PPI therapy should be administered for GERD patients who continue to have symptoms after PPI is discontinued, and in patients with complications including erosive esophagitis and Barrett's esophagus. (Strong recommendation, moderate level of evidence). For patients who require long-term PPI therapy, it should be administered in the lowest effective dose, including on demand or intermittent therapy. (Conditional recommendation, low level of evidence)

10. H₂-receptor antagonist (H₂RA) therapy can be used as a maintenance option in patients without erosive disease if patients experience heartburn relief. (Conditional recommendation, moderate level of evidence). Bedtime H₂RA therapy can be added to daytime PPI therapy in selected patients with objective evidence of night-time reflux if needed, but may be associated with the development of tachyphylaxis after several weeks of use. (Conditional recommendation, low level of evidence)

11. Therapy for GERD other than acid suppression, including prokinetic therapy and/or baclofen, should not be used in GERD patients without diagnostic evaluation. (Conditional recommendation, moderate level of evidence)

12. There is no role for sucralfate in the non-pregnant GERD patient. (Conditional recommendation, moderate level of evidence)

13. PPIs are safe in pregnant patients if clinically indicated. (Conditional recommendation, moderate level of evidence)

Note: Summary and Strength of Recommendation for GERD (Katz, P., Gerson, L. & Vela, M., 2013, p. 309).