PROTON PUMP INHIBITOR DEPRESCRIBING ALGORITHM EDUCATION IN AN OUTPATIENT PRIMARY CARE SETTING

by

Kimberlie Shiow Wang

A DNP Project Submitted to the Faculty of the

COLLEGE OF NURSING

In Partial Fulfillment of the Requirements

For the Degree of

DOCTOR OF NURSING PRACTICE

In the Graduate College

THE UNIVERSITY OF ARIZONA

2 0 1 9

THE UNIVERSITY OF ARIZONA
GRADUATE COLLEGE

As members of the DNP Project Committee, we certify that we have read the DNP project prepared by Kimberlie Shiow Wang, titled Proton Pump Inhibitor Deprescribing Algorithm Education in an Outpatient Primary Care Setting and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.

Jennifer Ruel DNP, FNP-BC, ENP-BC _____ Date: Nov 19, 2019
Jennifer Ruel, DNP, RN, FNP-BC, ENP-BC

_____ Date: Nov 19, 2019
S. Renee Gregg, DNP, FNP-C

Lauren Shurson _____ Date: Nov 19, 2019
Lauren Shurson, DNP, FNP-BC, BSN

Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College.

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.

Jennifer Ruel DNP, FNP-BC, ENP-BC _____ Date: Nov 19, 2019
Jennifer Ruel, DNP, RN, FNP-BC, ENP-BC
DNP Project Committee Chair
College of Nursing

TABLE OF CONTENTS

TABLE OF CONTENTS – *Continued*

TABLE OF CONTENTS – *Continued*

LIST OF FIGURES

ABSTRACT

Background: Proton pump inhibitors (PPIs) are one of the most commonly prescribed class of medication worldwide and are used for various indications as they work to suppress gastric acid secretion. Recent studies have identified adverse effects associated with long-term PPI use including anemia, pneumonia, kidney disease, osteoporosis, myocardial infarction, and *Clostridium difficile* infection. A needs assessment was conducted at an Oregon City, Oregon primary care clinic to determine the PPI prescribing and deprescribing practices. The findings suggest that the clinic may benefit from an intervention aimed at increasing PPI deprescribing.

Purpose: The purpose of this quality improvement project was to implement an evidence-based PPI deprescribing algorithm and educational presentation at an outpatient primary care clinic. The aim of this project was to determine the providers' (n=6) attitudes towards the algorithm.

Methods: A five-minute evidence-based PowerPoint presentation for all clinic provider participants regarding the significance of the clinical issue, current literature, and the algorithm was done at a staff meeting. A pre and post-intervention survey utilizing the 5-Point Likert scale was distributed to determine providers' attitudes.

Results: All participants believed their knowledge was enhanced by the educational session and algorithm and intend to use the algorithm in their future PPI deprescribing practice.

INTRODUCTION

Proton pump inhibitors (PPIs) are a class of medication that act to suppress gastric acid secretion and are widely used for various indications. Today, PPIs are one of the most frequently prescribed class of drugs worldwide (Masclee, Sturkenboom, & Kuipers, 2014)**.** As the adverse effects of PPIs are not commonly observed in patients, PPIs are regarded as safe, low-risk, and clinically beneficial. Furthermore, the task of lowering doses or discontinuing can be challenging due to recurrence of symptoms. The rate of recurrence increases without the addition of non-pharmacologic interventions including weight loss or dietary changes (Sandu & Fass, 2018). Recent pharmacoepidemiologic studies have uncovered adverse risks associated with the long-term use of PPIs (Corsonello et al., 2018). These findings, along with unnecessary financial expenditure, greatly support the need to identify patients who are inappropriately taking PPIs and deprescribe safely.

Background

Today, expenditures for PPIs fall only behind the cholesterol-lowering medication 'statins,' with an annual estimated cost of nearly $11 billion in the United States. The most common indications for PPI therapy are gastroesophageal reflux disease and gastric ulcer prevention (Heidelbaugh, Kim, Chang, & Walker, 2012). Only within the past fifteen years has the issue of PPI over-prescribing, in both the inpatient and ambulatory setting, captured the interests of researchers and healthcare providers alike due to emergence of new studies, especially when pertaining to long-term use (Strand, Kim, & Peura, 2017). Overutilization of PPI therapy is defined as use for a duration greater than the Food and Drug Administration (FDA)-

recommendation of four to eight weeks, as symptoms are generally well controlled after 60 days of therapy.

Studies surveying physicians to understand related knowledge and perceptions have revealed that barriers to PPI deprescribing include resource limitations, poor care coordination, and incomplete documentation of drug indications (Anderson, Stowasser, Freeman, & Scott, 2014). Moreover, qualitative surveys reveal that physicians report a lack of time to determine indication contributes to inappropriate continuation of PPIs. This is compounded by the idea that PPIs are generally thought of as a low-risk medication (Koczka, Geraldino-Pardilla, & Goodman, 2013). The Al-Qaisi and colleagues (2018) comprehensive, cross-sectional electronic survey assessed providers' knowledge and attitudes toward the reported adverse effects of PPI use and compare prescribing practices. The survey was distributed electronically to medical providers at an academic medical center in a metropolitan city. The 94 medical providers who responded include: resident and fellow trainees, nurse practitioners, physician assistants, and consultants across various specialties practicing in either the inpatient or outpatient setting (Al-Qaisi et al., 2018). Among the surveyed providers, a significantly larger percentage of gastroenterologists (GI) versus non-GI providers reported changing their prescribing practices of long-term use due to the reported adverse effects of PPI therapy Moreover, more GI providers opted to lower the PPI dose, while non-GI providers would be more likely to discontinue the PPI and initiate an H2 blocker. The majority of surveyed providers agreed that educational sessions would be beneficial in addressing challenges involving PPI prescribing and deprescribing (Al-Qaisi et al., 2018).

Significance of the Clinical Issue

Publication of literature examining both disease-related and financial outcomes of PPI use has captured the attention of healthcare professionals, patients, and the media. A retrospective analysis found that inappropriate use of PPIs post-hospital discharge was discovered in 2,160 patients based on ICD-9 codes, leading to a four-year cost of $617,007 USD (Leri et al., 2013). Potential risks associated with long-term PPI use based on observational studies include dementia, pneumonia, kidney disease, osteoporosis, myocardial infarction, *Clostridium difficile* infection, and micronutrient deficiencies among others (Strand et al., 2017).

Multiple studies have been performed to quantify the percentage of inappropriately prescribed PPIs. A 2010 analysis performed at a veteran outpatient clinic found that, of the 946 patients included in the study, 49% of PPI prescriptions were continued without re-evaluation of gastrointestinal symptoms, removing the potential for deprescribing therapy (Heidelbaugh, Goldberg, & Inadomi, 2010). A 2015 observational study conducted in multiple inpatient medical wards identified over-prescribing of PPIs in 73.9% of patients older than 75 years (Delcher, Hily, Boureau, Chapelet, Berrut, & de Decker, 2015).

The potential adverse effects of long-term PPI use can range from electrolyte imbalances to dementia. A 2013 case-control study conducted on a large sample size (n=210,155) in a community-based setting attempted to compare the incidence of vitamin B12 deficiency in association with PPI use (Lam, Schneider, Zhao, & Corley, 2013). The study showed that PPI use for at least two years was significantly associated with a new diagnosis of vitamin B12 deficiency, particularly in women and younger participants. The proposed mechanism is that the inhibition of acid release decreased acid-activated digestion of proteins

within the stomach, and thus an overall reduced absorption of essential vitamins (Eusebi et al., 2017). A similar mechanism is suggested to contribute to the increased risk of osteoporosis in patients on long-term PPI therapy as calcium absorption in the small intestine is decreased (Eusebi et al., 2017).

The Sehested et al. (2016) cross-sectional study aimed to examine the dose-dependent relationship between long-term use of PPIs and risk of ischemic stroke or myocardial infarction. Danish residents identified through a national health registry who had performed an endoscopic procedure without a history of cardiovascular or cerebrovascular disease, and were prescribed a PPI for at least six months were included. Of the 214,998 individuals who met the inclusion criteria with a median follow-up of 5.8 years, 7916 experienced an ischemic stroke, while 5608 had myocardial infarctions (MI). The results demonstrated that current use of PPIs was associated with a significantly higher risk for both ischemic stroke and MI. Furthermore, using a high PPI dose increased that risk even more (ischemic stroke hazard ratio 1.31; 95% confidence interval 1.21–1.42/myocardial infarction hazard ratio 1.43, confidence interval 1.30–1.57). Long-term PPI users had an almost 30% increased absolute risk of ischemic stroke, and an almost 40% increased risk of having an MI compared to non-users. Preclinical studies have demonstrated that a possible mechanism for increased cardiovascular or cerebrovascular even was due to a PPI-mediated reduction of nitric oxide synthase leading to endothelial dysfunction (Sehested et al., 2017).

Lambert and colleagues (2015) performed a systematic review and meta-analysis including cases of community acquired pneumonia (CAP) and PPI use from 26 studies. The study found a significant risk of CAP related to PPI use, particularly during the first month of

therapy irrespective of dosage or participant age (OR 1.49; 95% CI 1.16–1.92). Moreover, in participants who developed pneumonia, PPI use increased the risk of needing inpatient treatment. Experts suggest that the less acidic environment allows for overgrowth of bacterial organisms, and through mechanisms of aspiration or translocation, the bacteria can migrate into the respiratory system (Eusebi et al., 2017). It should be acknowledged, however, that the studies included were highly heterogenous.

The education of primary care providers on appropriate PPI use in alignment with best practice is critical for the reduction of patient exposure to unnecessary adverse effects and lowering healthcare cost. A retrospective study concluded that the total estimated inpatient and outpatient cost from inappropriate PPI use in a three-month period was $12,272 and $59,272, respectively (Ladd, Panagopoulos, Cohen, Mar, & Graham et al., 2014). A cross-sectional study investigating data collected from a 2004 National Nursing Home Survey attempted to identify predictors of non-evidence-based PPI use among US nursing home residents (Rane, Guha, Chatterjee, & Aparasu, 2017). The results concluded that residents residing in a micropolitan, or an urban area with between 10,000-50,000 residents, (aORs: 0.79, 95% CI: 0.63-0.98) versus metropolitan area, had a lower risk of being prescribed PPI therapy for a nonevidence-based indication. Furthermore, Medicare versus non-Medicare residents had an increased risk of being prescribed PPI therapy without an appropriate indication (aORs: 1.23, 95% CI: 1.01-1.50). In 2016, Oregon had almost 755,000 Medicare beneficiaries with almost 80% of those enrolled residing in a metropolitan area (Centers for Medicare & Medicaid Services, 2016). The region demographics may place Oregonians at an increased risk of inappropriate use of PPIs.

Local Problem

Primary care providers are responsible for performing medication reconciliation with patients during office visits. Medication reconciliation is defined as the process of ensuring the patient medication list is accurate and up to date, including drug name, dose, route, frequency, indication, and appropriateness (Institute for Healthcare Improvement [IHI], 2019). The medication reconciliation process can be an appropriate time to consider deprescribing medications as well. Deprescribing medications is the practice of tapering or discontinuing medication with the purpose of managing polypharmacy and improving patient outcomes (Thompson & Farrell, 2013).

This project investigator performed a needs assessment at the implementation site to examine the clinical issue of PPI overuse within the clinical setting. The electronic health record (EHR) of all patients seen at the clinic on the first Monday of each month in the three months prior to the expected project implementation date was reviewed. The project investigator had access to the EHR as she is currently completing a clinical rotation at the site. Permission to audit the chart during these dates for the purpose of the project was obtained from the clinic manager and site (Appendix A).

Patients who were seen in clinic on the three selected dates in May, June, and July 2019, and were prescribed a PPI based on their medication list were included in the project and reviewed for further analysis. Patient gender and age was collected. The name of the PPI medication, date it was originally prescribed, and indication was also recorded. The project investigator determined whether an appropriate PPI indication is associated with a documented diagnosis on the problem list. To determine appropriateness, the project investigator utilized

current FDA-approved product labeling for two PPIs, Omeprazole and Pantoprazole (Figure 1 & 2). The FDA label is congruent with the indications within the algorithm. Whether there is an appropriate indication may be listed as unclear if there is no documentation regarding need for maintenance of healing esophagitis. If the indication is considered inappropriate based on the FDA label, an audit of primary care notes within the past year was reviewed to determine if attempts to deprescribe were made. No identifying data or protected health information will be recorded during the EHR audit.

----------DOSAGE AND ADMINISTRATION----------

Indication	**Omeprazole Dose**	**Frequency**
Treatment of Active Duodenal Ulcer (2.1)	20 mg	Once daily for 4 weeks. Some patients may require an additional 4 weeks
***H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence (2.2)**		
Triple Therapy:		
PRILOSEC	20 mg	Each drug twice daily for 10 days
Amoxicillin	1000 mg	
Clarithromycin	500 mg	
Dual Therapy:		
PRILOSEC	40 mg	Once daily for 14 days
Clarithromycin	500 mg	Three times daily for 14 days
Gastric Ulcer (2.3)	40 mg	Once daily for 4 to 8 weeks
GERD (2.4)	20 mg	Once daily for 4 to 8 weeks
Maintenance of Healing of Erosive Esophagitis (2.5)	20 mg	Once daily
Pathological Hypersecretory Conditions (2.6)	60 mg (varies with individual patient)	Once daily
Pediatric Patients (1 to 16 years of age) (2.7) GERD And Maintenance of Healing of Erosive Esophagitis	Weight / Dose 5 < 10 kg / 5 mg 10< 20 kg / 10 mg ≥ 20 kg / 20 mg	Once daily

FIGURE 1. Food and drug administration dosage and administration of omeprazole

DOSAGE AND ADMINISTRATION

Indication	Dose	Frequency
Short-Term Treatment of Erosive Esophagitis Associated With GERD (2.1)		
Adults	40 mg	Once Daily for up to 8 wks
Children (5 years and older)		
≥ 15 kg to < 40 kg	20 mg	Once Daily for up to 8 wks
≥ 40 kg	40 mg	
Maintenance of Healing of Erosive Esophagitis (2.1)		
Adults	40 mg	Once Daily
Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome (2.1)		
Adults	40 mg	Twice Daily

FIGURE 2. Food and drug administration dosage and administration of pantoprazole.

The purpose of collecting this data was to perform a needs assessment, and ultimately inform providers of the volume of patients who may be on a PPI for an inappropriate or undocumented indication. Eighteen patients met the inclusion criteria, and 11 were prescribed Omeprazole, while seven were prescribed Pantoprazole. Thirteen of the 18 had gastroesophageal reflux disease listed as the indication. Only four patients had prescribers attempt to deprescribe or discontinue the PPI in the past year. This data will be presented at the educational session to provide insight on current clinic practices and validate the need for an intervention (Appendix B). The EHR audit data demonstrates a local and timely need to complete the project within this clinic.

Purpose

The purpose of this quality improvement project was to implement an evidence-based algorithm and educational intervention to effectively guide primary care providers in their PPI

deprescribing practices at an Oregon City, OR outpatient primary care clinic. The aim of this project was to determine provider attitudes towards a PPI deprescribing algorithm through surveying, and whether or not they intend to utilize the tool in their practice. Stakeholders involved in the use of the algorithm include healthcare providers and clinic manager within the clinic. Advanced practice registered nurses (APRNs) should have an interest in this project because they are dedicated to the comprehensive needs of their patients including the disease process, outcomes, patient education, and financial needs. Furthermore, APRNs are able to act as leaders in effecting healthcare change that focuses on health promotion, risk reduction, and disease prevention.

Study Question

What are primary care provider's attitudes toward an educational based intervention introducing an algorithm on PPI deprescribing, and will the provider intend to utilize the algorithm in their practice?

Theoretical Framework

The Stetler model was first developed in 1976 as the Stetler-Marram Model of Research Utilization (Stetler, 2001). The initial intention for the model was to place emphasis on the individual practitioner acting as the change agent and critical thinker instead of a group or organization. Eventually, the model was reformed and evolved, inspired by concepts related to research and knowledge utilization (Stetler, 2001). The Stetler model now aims to apply evidence into daily practice. The practitioner-oriented model focuses on guiding providers to implement formal changes supporting safe and effective patient care. As this project aims to

implement an evidence-based algorithm and educate providers on best PPI prescribing and deprescribing practices, the Stetler model will act as an effective and relevant framework.

Composed of five phases, the Stetler model is designed to encourage critical thinking (Rycroft-Malone & Bucknall, 2011). The phases include preparation, validation, comparative decision making, translation, and evaluation. The preparation phase involves identifying the problem and qualifying the issue with evidence. During the validation phase, synthesizing available literature and appraisal of the findings are done. A table should be created during this phase to grade and critique the evidence (Rycroft-Malone & Bucknall, 2011). Final synthesis of the evidence occurs in the comparative decision-making phase. Here, the user must decide what evidence is appropriate, and if conducting further research is applicable or needed. A proposal for the practice change is developed during the translation phase along with identifying strategies for knowledge dissemination. Formative and summative evaluations of the change, including considerations of cost, occur in the fifth and final phase (Rycroft-Malone & Bucknall, 2011).

The Stetler model specifies measures to determine the appropriateness and practicality of applying evidence to a clinical issue. The first criterion is ensuring the existence of substantiating evidence and examining the current practice (Stetler, 2001). Next, suitability of the substantiated evidence for the population and environment is assessed. The last criterion involves evaluating feasibility of implementing the evidence by performing a risk-benefit assessment, consideration of available resources, and determining stakeholder readiness (Stetler, 2001).

Application of the Stetler Model and Other Concepts

Preparation

In this phase, the project investigator performed a literature review to recognize the magnitude of inappropriate PPI use within the outpatient setting. The extensive volume of literature addressing this issue was helpful in providing the practitioner with useful information. The project investigator evaluated the PPI deprescribing practice and culture at the clinical site in which the intervention will be implemented.

Validation

After a thorough literature review was completed and evidence had been collected, each source was critiqued for "its level of overall credibility, applicability and operational details" (Stetler, p. 273, 2001). The strength and weakness of the evidence was appraised using the GRADE framework, as well as its suitability to be synthesized with the other sources. It is essential to thoroughly appraise the recommendations to be included and examine outcomes and learnings from clinical sites who attempted a similar intervention. Lastly, during the validation phase, the evidence was summarized in an applicable synthesis of findings. The findings were presented at the educational session to support why utilization of the PPI deprescribing algorithm is necessary and relevant.

Comparative Decision-Making

This phase is opportune for considering barriers and organizational factors before further progression. For example, as this is a proposed practice change, barriers would include opposition from staff whom are resistant to inclusion of new tools due to fatigue from a surplus of resources. Staff who are unfamiliar with the recent literature surrounding adverse effects from

chronic PPI therapy may choose not to adopt the intervention, rendering the change to be unsuccessful and incomplete. The organizational factors include assessing staff attitudes toward allotting time to implementing this change. If this clinical issue is not viewed as a priority, and without stakeholder buy-in, a lack of support may lead to project failure. During this phase, consideration of the concepts discussed previously was pertinent. Moreover, the introduction of a user-friendly algorithm during an evidence-based educational session encouraged stakeholder support.

Translation

The project investigator then translated the statement of findings into an actionable study design. The change is considered a direct instrumental use of evidence because it is the concrete implementation of a tool to support best PPI prescribing practices. Dissemination of the evidence occurred during this phase, as well as employment of change strategies. Theorist Everett Rogers noted that to successfully disseminate knowledge and persuade stakeholders to adopt change, enhancement of personal credibility is an effective change strategy (Rogers, 2003). Elevating credibility as a change agent can be done through evaluation of one's leadership style. An authentic leader possesses self-awareness and alignment of personal and professional values. The authentic leader has the capability to foster "open, transparent, trusting and genuine relationships" (Avolio & Gardner, 2005, p.322).

Rogers also suggests that the formation of a positive or negative attitude is dependent on the level of uncertainty toward the value of the proposed change (Rogers, 2003). Recognizing this behavior encouraged the project investigator to employ the change strategy of appealing to

the potential benefits for stakeholders. The benefits were acknowledged during the educational session introducing the algorithm.

Evaluation

The last phase of evaluation required the project investigator to assess the change, formed attitudes, and desired or undesired outcomes. It is important to note that the credibility of a project investigator's evaluation is strengthened by observing for both formative and outcome data (Stetler, 2001). For purpose of credibility and transparency, the interpretation of results were reflected graphically and shared with providers.

Additional Concepts

In addition to the Stetler model, concepts of rational thinking, implementation science, and consistency within cognitive theories of change were utilized to guide this project. It is critical to consider these concepts when considering why providers do not prescribe or continue PPI therapy in adherence to clinical practice guidelines and recommendations. The assumption within rational decision-making theories is that providers must consider the advantages and disadvantages of alternative behaviors within their practice (Grol, Bosch, Hulscher, Eccles, & Wensing, 2007). Thus, the supplementation of convincing evidence related to the risks and benefits surrounding a clinical issue is crucial for changing practice behaviors, and, thus was a prioritized strategy included in the educational session.

There are cognitive theories that describe the conceptual mechanism of consistency that may prevent rational decision-making. Moreover, that in favor of consistency, providers may disregard valuable evidence or seek evidence that confirms their beliefs for preserving existing opinions and behaviors (Grol et al., 2007). Thus, introducing the algorithm alongside

a brief educational session on the scope of the clinical issue was necessary to overcome the preference of consistency.

Acknowledging these concepts encouraged this project investigator to identify implementation science strategies that would be effective for the target audience. Implementation science suggests that guidelines and proposed change are more likely to be successfully adopted if algorithmic or graphical tools are provided (Gagliardi, Brouwers, Palda, Lemieux-Charles, & Grimshaw, 2011). Literature has shown that lack of comprehensible tools and local applicability act as barriers to guideline use by providers. In conclusion, consideration of these aforementioned factors heavily guided the project investigator as she developed her educational presentation to encourage stakeholder buy-in and project outcomes.

Synthesis of Evidence

A synthesis of evidence was performed assessing the efficacy of PPI deprescribing interventions used within various clinical settings. A review of the literature using Google Scholar and PubMed was conducted for the years 2013 through 2019. Key words included combinations of "PPI," "PPI therapy," "proton pump inhibitor," "deprescribing protocol," "discontinuation" or "decreasing dose." MeSh headings in PubMed included: "Adverse effects," "Statistical and numerical data" and "Supply and distribution." The following limits: full text availability, English language, and publication within the last six years were applied to the search. Studies were included if the primary or secondary outcome was to decrease dosing or discontinue PPI therapy within an inpatient or outpatient clinical setting. The initial search yielded 72 articles. Articles were excluded if they did not closely relate to deprescribing PPIs or

did not utilize a specific intervention. Ten articles were retained as relevant to the project's purpose and were critically appraised with the findings summarized (Appendix C).

Efficacy of Deprescribing Algorithms

Of the ten studies appraised, four of the studies implemented a PPI deprescribing algorithm. The Thompson et al. (2016) interrupted time-series analysis aimed to compare change in monthly PPI usage and average monthly PPI cost before and after guideline implementation in an eastern Canada long-term care home. The total number of PPI prescriptions each month was monitored nine months before the guidelines were implemented and then for 12 months after. A total of 335 residents received PPI therapy over the 21-month period. The results demonstrated that implementation of a deprescribing guideline and support tool did lead to a decrease in PPI prescribing, however, the reduction primarily occurred within the first six months following intervention introduction. PPI prescribing gradually increased in the remainder of the analysis period, and overall there was not a significant reduction in use. The authors noted there was a significant increase in deprescribing events after the implementation, as well as a significant decrease in average monthly PPI cost (Thompson et al., 2016).

A prospective study was performed by Reeve and colleagues (2015) assessing the feasibility of a patient-centered PPI deprescribing process through recruitment of 57 PPI users at outpatient clinics in southern Australia. The deprescribing process consisted of five steps including: determining medication history, identification of inappropriate medications and potential for discontinuation, outlining the deprescribing plan including necessary monitoring, support, and documentation. Feasibility was determined by assessing the time required for completion of the deprescribing process and participant feedback. Of the 57 PPI using

participants, the indication for PPI use was verified as potentially inappropriate in 44%. Of the eight that were considered appropriate for PPI deprescribing, six consented to the process. All six participants successfully ceased or reduced PPI use, and 66% continued to do so at the six-month follow-up (Reeve et al., 2015).

The Avraham and Bigelow (2018) pilot study attempted to implement a step-based PPI deprescribing protocol in a nursing home between April and June 2017. Ten residents met the inclusion criteria for the study in which outcomes of hospital admission, rebound hypersecretion, gastrointestinal symptom scores, and participant feedback were assessed. The study found that the residents did not report increased gastrointestinal symptoms, had no significant changes in cachexia, emesis, anemia, dysphagia or agitation, and laboratory values including guaiac tests remained relatively consistent while average medication burden decreased.

Walsh and colleagues (2016) developed a 10-week prospective, descriptive quality improvement project using a PPI deprescribing tool developed from a review of current guidelines. The tool was introduced to providers as well as uploaded into the electronic health record. Forty-six patients met the inclusion criteria to participate, and 74% (n = 34) had a documented indication. Of the 46 patients, 43 had their PPI reassessed, and 26% had their PPI deprescribed.

Efficacy of Pharmacist-Led Interventions

Implementation of pharmacist-led interventions accounted for 50% of the studies. Moreover, a pharmacist was responsible for either developing or following a PPI deprescribing protocol, reviewing the medications of study participants, and creating recommendations for providers in their PPI prescribing practice. In some studies, pharmacists were allowed to

deprescribe without physician action (Michal et al., 2016). The Luo and colleagues retrospective observational study (2016) implemented management policies and clinical pharmacist interventions at a large public hospital in the South Sichuan Province between March and December 2016. During the post-intervention period, electronic health record audits indicated that the rate of inappropriate PPI prescribing decreased from 73.37% to 56%.

Wahking and colleagues (2018) aimed to evaluate the impact of an inpatient PPI stewardship program on the percentage of patients who had inpatient or outpatient PPI discontinuation or decreased dosing. The retrospective cohort study was performed from March to August 2016 on all admitted internal medicine patients at a Kentucky hospital. During this time, 537 patients with an active outpatient PPI prescription were admitted, and 41.0% did not meet criteria for continuation. After discontinuation, 83.4% did not require as-needed acid suppression therapy during their hospitalization, and 95.9% tolerated cessation. The study found that 57.1% of patients were able to tolerate PPI discontinuation three months after discharge, and 81.8% of patients tolerated the decreased PPI dose. Therefore, the study concluded that a PPI stewardship program resulted in significant reduction of inappropriate inpatient and outpatient PPI use (Wahking et al., 2018).

Clinical pharmacists participating in the Bundeff and Zaiken (2013) prospective observational study reviewed patient medical records for study inclusion and sent recommendations for PPI tapers to primary care providers. Some 302 taper recommendations were sent during the two-month study period. The results demonstrated a statistically significant decrease in mean pills per month count from 25.6 pills at baseline to 16.9 pills at follow-up. At least 31% of participants were able to fully taper off their PPI therapy at the study conclusion,

while 26% were able to fully taper off with intermittent histamine-2 receptor antagonists or antacid therapy for symptom management. And 7% of participants had a partial PPI taper during the study period (Bundeff & Zaiken, 2013).

The Lee and colleagues (2017) quality improvement project aimed to deprescribe PPI therapy at a residential care facility. A pharmacist would examine whether residents who had been taking a PPI therapy for at least six months had an appropriate indication. Following this, pharmacists would recommend to the physician either discontinuing, tapering, or changing to histamine-2 receptor antagonist based on the PPI deprescribing algorithm of the Ontario Pharmacy Research Collaboration. Follow-up to assess for adverse events related to deprescribing was done by pharmacists weekly for eight weeks. Of the 37 residents whom had been taking PPIs for longer than six months, 28 met the criteria for discontinuation. Eight weeks after discontinuing PPI therapy, 70% of the 27 participants remained asymptomatic and did not require return of therapy (Lee et al., 2017).

The Michal, Henry, and Street (2016) pre-post intervention study performed at a non-intensive care hospital aimed to decrease PPI usage in patients at least 18 years of age admitted to a general medical surgical unit. The protocol was used by pharmacists who would review PPI indication and appropriateness. Based on the protocol, pharmacists would recommend to the attending provider for PPI discontinuation or switching to a histamine-2 receptor antagonist. In the pre-intervention group, 35 of the 49 patients had their PPI discontinued. Ninety-four patients were included in the post-intervention, and 62 patients were able to have their PPI discontinued. This represents an absolute risk reduction of 24.9% (Michal et al., 2016).

Efficacy of Web-Based Tools and Educational Sessions

McDonald and colleagues (2015) designed a before-and-after study introducing a monthly educational intervention combined with a web-based quality improvement tool to providers at a medical unit in Montreal, Canada. The purpose of the study was to decrease inappropriate PPI therapy in hospitalized patients. At the start of each academic period, an information session addressing the benefits and harms of PPI use, as well as how to use the web-based tool, was held for incoming resident physicians. The online tool guided resident physicians in evaluating appropriateness of use during the routine medication reconciliation process. The tool also presented the option of discontinuing PPI therapy upon discharge in the absence of an appropriate indication.

The study was divided into a six-month pre-intervention control period and six-month intervention period (McDonald et al., 2015). During the pre-intervention phase, 45% of the 464 patients were prescribed a PPI therapy prior to admission. In addition, 53 patients were newly prescribed a PPI that was continued upon discharge. In comparison, during the intervention phase, 44% of the 640 admitted patients were prescribed a PPI prior, and 60 patients were newly prescribed a PPI that would be continued after discharge. After the intervention, there was a clinically and statistically significant increase in the proportion of discontinued preadmission PPIs at discharge (McDonald et al., 2015).

Strengths and Limitations

All study designs were a level III or lower quality of evidence. However, given that all appraised studies demonstrate consistent results that the interventions may reduce occurrence of inappropriately prescribed PPI therapy, the recommendation of implementing an educational or

algorithmic intervention receives a Grade B (Burns, Rohrich, & Chung, 2011). The majority of the studies present the limitation of lacking a control group to minimize effects from other variables and small sample size. A strength of all studies would be ease of replicability and adaptability to be used in a variety of settings, along with low financial cost for implementation.

The Thompson et al. (2016) study is limited in that it fails to address covariates including age, gender, duration of PPI use or indication that may impact findings. The design does address the factors of history and maturation as threats to external validity through several assessments of the outcome measures both prior to and after the intervention. Limitations of the Reeve and colleagues (2015) study include author self-report of possible bias or conflict of interest and incomplete medical histories obtained to prevent the presence of confounding variables. Limitations of the Avraham and Bigelow (2018) study include poor generalizability due to complex poly-morbidity and polypharmacy.

The Wahking and colleagues (2018) study is limited in that it consisted of primarily male veterans. A highly homogenous population reduces generalizability to other populations. Additionally, follow-up on successful adherence to PPI discontinuation or decreased dose at three months does not demonstrate if the outcome can persist long-term.

A limitation of the McDonald et al. (2015) study is the external validity threat of maturation. The practice of resident physicians is known to evolve dramatically during the beginning years of their medical training. As the implementation occurred at the beginning of the academic year, it is unclear as to how the trainees may become more or less receptive to the intervention as time progressed. Furthermore, relying on the resident physicians to consistently

use the tool as a means of data collection proved difficult and unreliable primarily due to demands on their time.

Lastly, as multiple pharmacists were responsible for assessing symptom reoccurrence in the Lee et al. (2017) study without the use of a validated tool, interobserver variation acts as a limitation in affecting results. Interobserver variation is defined as the discrepancy that may occur due to a single observer reporting more than once on the same data (Popovic & Thomas, 2017). Furthermore, a follow-up period of only eight weeks may be too short to accurately detect a return of gastrointestinal symptoms.

Summary of Evidence

All of the studies consistently demonstrate that the inappropriate use of PPI therapy is common within the inpatient and outpatient setting. The studies were able to evaluate the efficacy of a PPI deprescribing intervention with varying statistical significance. However, there is a need for future research to be done with designs reflecting a higher level of evidence in larger sample sizes to further support the recommendations. As the prevalence of increased co-morbidities and polypharmacy continues to escalate, so does the need to engender a culture of responsibility for all prescribed medication

METHODS

Project Design

A pre-post interventional descriptive study design was utilized to assess primary care providers' attitudes toward a PPI deprescribing algorithm educational intervention implemented at a primary care clinic in Oregon City, Oregon. The algorithm was introduced to the providers

during an in-clinic educational session led by the project investigator. The educational session included an evidence-based PowerPoint presentation created by the project investigator.

Setting and Participants

This project investigator introduced the PPI deprescribing algorithm to providers at a Providence Medical Group primary care clinic in Oregon City, Oregon. This clinic is a part of the Providence Health & Services organization, a not-for-profit Catholic network of hospitals, care centers, clinics, home health care and affiliated services. The clinic has six practicing physicians (Providence Health & Services, 2019). These six providers acted as the study participants.

PPI Deprescribing Algorithm

The PPI algorithm used was adopted from the Bruyere Deprescribing Research Team (Appendix D). The team consists of physicians and pharmacists that work to create evidence-based deprescribing algorithms and guidelines to be used by providers for various classes of medications (Bruyere Research Institute, 2019). The PPI algorithm was developed in 2016 using systematic review and a GRADE approach and has been downloaded more than 2,000 times for use in various settings across the world. The algorithm begins with assessment of indication or lack thereof. Based on the indication and length of therapy, the next step encourages either lowering the dose, adjusting to on-demand therapy, or stopping the PPI altogether. Afterward, recommended duration for monitoring and follow-up management including non-drug interventions, treatment for occasional symptoms, or re-initiation of PPI therapy is detailed.

Data Collection

Educational Intervention

For the purpose of informed consent, all providers were given a disclosure statement prior to the educational session detailing the objective and tasks of the project (Appendix E). The project investigator developed and presented a five-minute evidence-based PowerPoint presentation for all clinic provider participants regarding the significance of the clinical issue and educated on current literature, needs assessment results and the algorithm (Appendix F). The PowerPoint included material obtained from the literature review and synthesis of evidence. The presentation occurred during a staff meeting. During the presentation, the information collected during the needs assessment and review of the EHR was shared, and served as a persuasive strategy for stakeholder buy-in. Immediately before beginning the presentation, the project investigator distributed two papers stapled together, containing the six-question pre-intervention survey and the three question post-intervention survey (Appendix G & H). The pre-intervention survey assessed provider knowledge and self-perceived confidence in PPI indication and deprescribing protocol, as well as individual deprescribing practices. Demographic questions were included in the pre-intervention survey including professional credential and years in practice. After the educational session, the project investigator asked the participants to answer the post-intervention survey to assess feedback regarding provider perceptions of the algorithm and intent for future use. Each survey required one to two minutes to complete. Provider perceived algorithm efficacy was measured as well as whether they intend to utilize the algorithm in their future practice. Thus, the project outcomes included algorithm usability,

providers' attitudes towards the algorithm and an intent to change their deprescribing practice pre- and post- intervention.

Ethical Considerations

There was no foreseeable risk to the project participants. A written agreement was obtained from the clinic provider demonstrating permission to perform the project (Appendix A). The DNP project may be exempt from requiring Institutional Review Board approval, and approval from the University of Arizona Human Subjects Protection Program was obtained (Appendix I).

Respect for Persons

The basic ethical principle of respect for persons within research argues that participants should be recognized as autonomous individuals. For research that involves human subjects to adhere to this principle, subjects must participate voluntarily and with adequate information (Office for Human Research Protections, 2018). Providers were informed of project aims and participant tasks. Providers were asked to voluntarily answer survey questions or watch the presentation. Furthermore, all survey answers were kept anonymous throughout the process.

Beneficence

The presence of beneficence is respected in research through absence of harm, maximization of benefits, and minimization of risk (Office for Human Research Protections, 2018). There are no risks in participating or performing the project, and no threats to safety. The simplicity of the pre-post interventional study design allowed for accomplishment of objectives. Furthermore, sharing the study results with providers was beneficial in that it

enhanced awareness surrounding practice culture within the clinic, and encouraged optimization of patient care.

Justice

There is no unfair targeting of a specific or vulnerable population. The inclusion criterion is fair and appropriate when considering examining the EHR as anyone who is taking a PPI will be assessed for a deprescribing event regardless of sex, race or other demographic variables. All clinic providers were given the opportunity to participate in the project and presented information, thus facilitating a design respecting equality.

Data Analysis

The responses collected from provider surveys served as quantitative data and were expressed using descriptive statistics shown as percentages using charts and graphs. Analysis of quantitative change between the pre and post intervention provider survey determined if providers felt more confident in their knowledge and ability to deprescribe PPIs after implementation of the algorithm. The post-intervention provider survey determined if the majority of participating providers found the algorithm beneficial, and if they plan to continue using it as a resource in their future practice. The participating providers were emailed a synopsis of the project results. This allows participants to determine if the data appropriately represents their practice and thoughts, a practice referred to as member checking (Polit & Beck, 2012).

RESULTS

Participant Demographics

The project investigator successfully completed the educational session at the staff meeting as planned on October 25, 2019, and all seven providers present voluntarily elected to participate after being provided a disclosure form. Pre-survey question one asked for the credentials of the participants, and question two asked for years in practice (Figure 3). Of the participants, one self-identified as a physician assistant and the remaining six participants were physicians. It should be noted that one of the participating physicians reported that she was a psychiatrist. She participated in the presentation and survey, however, given her limited role in managing gastrointestinal diseases or the prescribing of relevant medications, her data will not be included in the statistical analysis.

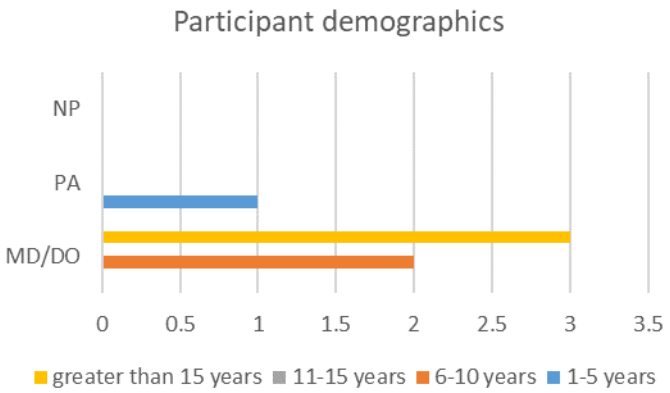


FIGURE 3. Participant demographics.

Pre-Intervention Survey

In the pre-intervention survey, the participants were given the option of using the five-point Likert scale (‘strongly disagree,’ ‘disagree,’ ‘neutral,’ ‘agree,’ ‘strongly agree’) to answer the questions. The first and second question asked demographic questions as described in the

section above. The third survey question asked participants if they routinely manage patients with gastroesophageal reflux disease (GERD), H.pylori, peptic ulcer disease, or similar gastrointestinal diseases. All participants either agreed (n=3) or strongly agreed (n=3) that they routinely manage patients with upper GI symptoms.

Next, participants were asked if they felt as if their knowledge of FDA-approved PPI indications and length of therapy was at the expert level. The majority of responders agreed that their knowledge of FDA-approved PPI therapy was at the expert level (n=4), with the exception of the physician assistant and one physician with greater than 15 years of experience who reported as neutral. The fifth and sixth questions had statements asserting: "I am confident in my ability to deprescribe a PPI appropriately," and "I routinely attempt to deprescribe PPI therapy in accordance with FDA recommendations." The same two participants, respectively, also reported that they felt neutral about their ability to deprescribe a PPI, and either disagreed or were neutral that they routinely attempt to deprescribe PPI therapy. The remaining respondents (n=4) agreed that they were confident in their ability to deprescribe a PPI appropriately, and that they routinely attempt to deprescribe PPI therapy. The answers to these questions are described in Figure 4.

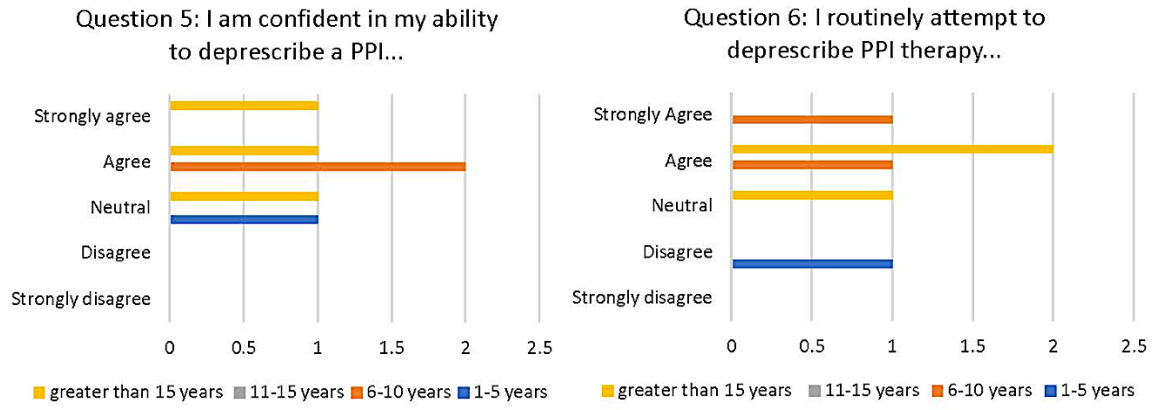


FIGURE 4. Questions 5 and 6 responses.

Post-Intervention Survey

In the post-intervention survey, the participants were again given the option of using the 5-Point Likert scale (‘strongly disagree,’ ‘disagree,’ ‘neutral,’ ‘agree,’ ‘strongly agree’) to answer the questions. The first question assessed whether the participants felt as if the educational session and algorithm enhanced their knowledge of FDA-approved PPI indications, length of therapy, and deprescribing protocol. All participants responded either agree (n=2) or strongly agree (n=4) to this question (Figure 5).

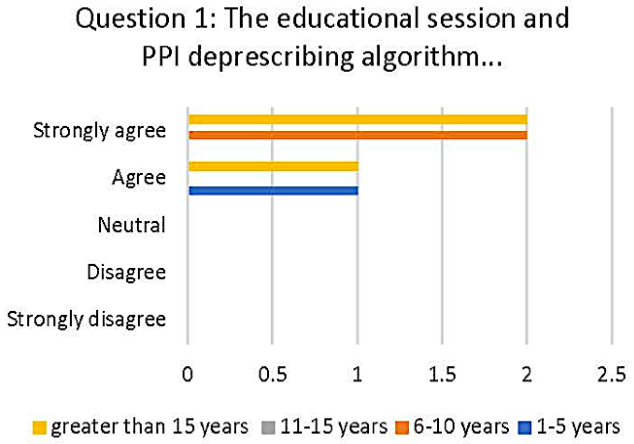


FIGURE 5. Question 1 responses.

The two who selected agree versus strongly agree were the physician assistant and a physician with greater than 15 years of experience. Next, the second and third question had statements asserting: “I believe the algorithm can encourage providers to attempt to deprescribe PPIs more frequently,” and “I intend to use this algorithm to help guide my PPI deprescribing practice in the future.” Also, 100% of the providers believed their knowledge was enhanced by the educational session and algorithm and intend to use the algorithm in their future practice (Figure 6).

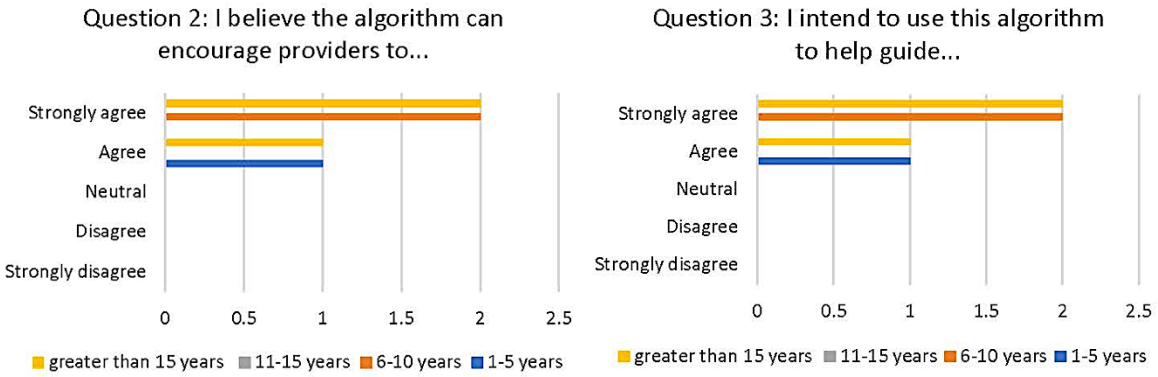


FIGURE 6. Questions 2 and 3 responses.

Given the participants overwhelmingly responded unilaterally to the post-survey questions, the data will be analyzed as dichotomous variables to answer the study question. Whether or not a provider had a positive or negative attitude is determined by whether they responded with agree or strongly agree versus disagree or strongly disagree. Whether or not a provider intends to use the algorithm is determined by whether they responded with agree or strongly agree versus disagree or strongly disagree.

Over 100% of survey respondents had a positive attitude toward the intervention and intend to the use the algorithm in their future practice. Two of the seven providers whom felt neutral in considering themselves as experts in their knowledge of PPI indications and therapy both felt that the intervention enhanced their knowledge in the post-intervention survey.

DISCUSSION

The results of the project reflect that providers responded positively toward educational outreach and algorithmic tools. As expected per the Stetler model and strategies of implementation science, providers responded favorably to an intervention utilizing clinical evidence presented in support of patient care outcomes and reducing healthcare expenditure.

Moreover, in alignment with concepts of rational thinking, providers formed a positive attitude to an intervention that emphasized the benefits of PPI deprescribing with a concise clinical tool.

The evidence collected through the conducted literature review and synthesis demonstrated that various interventions may reduce occurrence of inappropriately prescribed PPI therapy. However, none of the studies were able to qualify how providers felt about the intervention themselves, which can provide insight into expected sustainability. The outcomes of this project are consistent with current evidence in that providers do have an improved sense of self-efficacy when utilizing evidence-based deprescribing guidelines, and that the majority of providers believe that deprescribing is beneficial to patients (Farrell et al., 2018; Nadarajan, Balakrishnan, Yee, & Soong, 2018). This was demonstrated as all providers believed their knowledge was enhanced by the educational session and algorithm and intend to use the algorithm, representing stakeholder buy-in. The sustainability of evidence-based interventions and practices in healthcare is a growing topic of interest for research. Literature has identified stakeholder support as a core factor of sustainability (Chambers, 2015). Therefore, the project outcomes suggest that the algorithm may be sustainable and used effectively in other primary care clinic settings.

The growing issue of polypharmacy within modern medicine driven by an aging population with an increasing number of morbidities necessitates prioritization by healthcare providers. Thus, the impact of the project outcomes for future research or practice is the demonstration that successful deprescribing of inappropriate or unneeded medications may be accomplished through the use of educational outreach and algorithmic tools. Furthermore, that the creation of more evidence-based algorithms to be introduced within the clinical setting can

aid providers in their deprescribing practice. The algorithms can be introduced at staff meetings similar to this project, or input into the curriculum of continuing medical education (CME) lectures and seminars.

Strength and Limitations

A strength of this DNP project was that the intervention responded to an identified need of the clinic through auditing of patient medical records, thus increasing stakeholder buy-in. Additionally, through the use of the Stetler model and implementation science strategies, the educational session and algorithm was presented to appeal to the rational decision-making capacity of the providers, with a focus on improving patient care. Because of this, the outcomes of this project are what was to be expected. The years in practice of the providers were well distributed despite a small sample size, posing as a strength in reflecting opinions of providers in different stages of their career.

Limitations of this project include a small sample size, participant bias, and failure to collect follow up data to monitor for a quantitative increase in deprescribing events. As the project investigator was a student working with the clinic for many months, partiality to respond positively to survey questions, despite anonymity may be present. This is the issue of reactivity within a study in which participants alter behavior if aware they are being observed. Finally, the project is limited in that it provides no insight to whether the intervention had clinical significance.

Application of DNP Essentials

This DNP project was completed to fulfill the requirements of a doctoral program, with consideration of the foundational competencies and essentials of doctoral education for advanced

nursing practice. Overall, the second and third essentials are most relevant to the aim of this project. The second essential emphasizes organizational and systems leadership for quality improvement, which includes the practice of promoting patient safety in a target population. The third essential involves critical appraisal and translation of evidence to be disseminated and integrated into practice (American Association of Colleges of Nursing, 2006). This DNP project satisfies the second essential as the intervention was developed under a research utilization framework along with leadership, change, and implementation strategies that was based on a needs assessment. Furthermore, the aim of the project in deprescribing PPI therapy is to reduce polypharmacy, risk of medication adverse effects, and healthcare cost. The third essential was met as this project investigator synthesized evidence to educate healthcare providers and introduced a deprescribing algorithm to be utilized within clinical practice.

Plans for Dissemination

The project investigator obtained the participant's email addresses from the clinic manager and sent a summary of the results to the providers. The clinic was allowed to keep physical, laminated copies of the algorithm, which can be shared with more providers in the future. The outcomes will be discussed with the committee members of this project during a final project defense. A poster presentation will also be created for submission to the Western Institute of Nursing Conference.

Future Implications for Practice

The outcomes of this DNP project demonstrate that providers in this clinic were receptive to the inclusion of deprescribing algorithms in their practice as a way to reduce adverse medication effects and lower healthcare expenditure. These findings support present literature in

that education and algorithmic interventions may increase PPI deprescribing in the clinical setting. However, current literature is lacking in determining if the alterations in behavior or use of the algorithm is sustainable. Additionally, the associated factors contributing to sustainability should be understood as well including class of medication, method of introducing the algorithm, organizational incentives, or healthcare provider demographics. Therefore, conduction of retrospective studies to see the trends of deprescribing over a long period of time is needed to further support integration and creation of these clinical tools.

Conclusion

All participants of this QI project had a positive attitude toward the PPI deprescribing educational session and reported intention to the use the algorithm in their future practice. These results act as evidence to further support the use of deprescribing algorithms within the clinical setting as a means to reduce polypharmacy and related concerns at this clinic in Oregon City, OR. Further evaluation would demonstrate if the use of deprescribing algorithms leads to decreasing trends in polypharmacy and inappropriate medication use in the Providence Medical Group clinic in Oregon City, Oregon.

OTHER INFORMATION

Projected Budget

The budget (Appendix J) for this DNP project was relatively minimal, with costs relating only to the printing of algorithms for provider use as well as a small breakfast assortment provided at the educational session to encourage attendance. All costs for this project was contributed entirely by the project investigator.

APPENDIX A:

SITE AUTHORIZATION FORM

Providence Medical Group – Oregon City

1510 Division St
Oregon City, OR | 97045

August 6, 2019

University of Arizona Institutional Review Board
c/o Office of Human Subjects
1618 E Helen St
Tucson, AZ 85721

Please note that Ms. Kimberlie Wang, UA Doctor of Nursing Practice student, has permission of the Providence Medical Group-Oregon City to conduct a quality improvement project at our facility for her project, "PROTON PUMP INHIBITOR DEPRESCIBING ALGORITHM EDUCATION IN AN OUTPATIENT PRIMARY CARE SETTING."

Ms. Wang will audit the EHR to assess for prescribing of PPIs in clinic patients in compliance with HIPAA and without recording of patient identifiers, present a PowerPoint presentation on PPI deprescribing, and distribute a brief pre- and post- presentation survey to clinic providers.

Ms. Wang has agreed to provide my office a copy of the University of Arizona Determination.

If there are any questions, please contact my office.

Signed,

Jonny Bunn
Clinic Manager

APPENDIX B:

ELECTRONIC HEALTH RECORD TABLE

Electronic Health Record Table							
	Medication	**Indication**	**Start Date**	**Provider Last Review**	**Appropriate per FDA Recommendation**	**Was there an attempt to deprescribe?**	**Last Annual Exam**
65 yo male	20mg Omeprazole daily	GERD	December 2012	January 2018	Unclear	No	December 2018
60 yo female	40mg Pantoprazole daily	GERD	March 2019	June 2019	No	No	February 2019
66 yo male	40mg Omeprazole BID	Esophageal spasm	April 2019	April 2019	No	No	April 2019
65 yo male	20mg Pantoprazole daily prn	GERD	Unk.	October 2018	Yes	No	October 2018
73 yo male	40mg Pantoprazole daily	GERD	April 2011	February 2019	No	Yes	February 2019
76 yo female	20mg Pantoprazole daily	GERD	June 2019	June 2019	Yes	No	June 2019
46 yo female	20mg Omeprazole daily	Unk.	Unk.	Unk.	No	No	December 2018
24 yo female	40mg Pantoprazole daily	GERD	September 2018	September 2018	No	Yes	September 2018
64 yo female	20mg Omeprazole daily	GERD	March 2018	September 2018	Unclear	No	June 2019
63 yo male	20mg Omeprazole daily	GERD	February 2015	February 2016	Unclear	No	June 2019
73 yo male	20mg Omeprazole daily	GERD	February 2015	April 2018	Unclear	No	April 2018
73 yo male	40mg Pantoprazole daily	GERD	April 2011	February 2019	No	Yes	February 2019
68 yo female	20mg Omeprazole	Epigastric pain	February 2019	February 2019	No	No	March 2019
70 yo female	20mg Omeprazole	GERD	July 2017	July 2019	Unclear	No	July 2019
76 yo male	20mg Omeprazole	GERD	August 2012	May 2019	Unclear	No	May 2019
85 yo male	20mg Omeprazole	GERD	March 2015	May 2018	Unclear	No	May 2018
73 yo female	20mg Omeprazole	Abdominal pain	May 2019	May 2019	Yes	Yes	May 2019
87 yo female	40mg Pantoprazole BID	Upper GI Bleed	May 2019	May 2019	Yes	No	May 2019

GERD = Gastroesophageal reflux disease GI = gastrointestinal BID = twice a day Unk. = Unknown
FDA = Food and Drug Administration yo = years old

APPENDIX C:

TABLE OF EVIDENCE

Summary of Findings from Literature Review on the Efficacy of Education and Clinical Decision Tools or Algorithms on the Deprescribing of PPI Therapy Across Multiple Clinical Settings

Authors & Year	Purpose	Design, Sample, & Setting	Findings
Avraham & Bigelow, 2018	Establish and implement a stepwise taper protocol to decrease overuse of PPI therapy in a nursing home	Pilot study Only n =10 (mean age 65.6yo) of 67 residents qualified for enrollment Urban nursing home providing short- and long-term skilled care for older residents	- 90% of patients achieved cessation at 12 weeks
Bundeff & Zaiken, 2013	Evaluate the impact of pharmacist to clinician recommendations to decrease inappropriate chronic PPI use	Prospective observational study n = 302 patients were appropriate for taper recommendations (29.1% male, mean age: 57.4yo) Atrius Health, a nonprofit organization serving over 700,000 patients in Massachusetts across 24 sites	- Average pills/month count decreased by 8.7 pills (95% CI: 6.4, 11.1) - For the 117 evaluable patients, the annualized PPI cost decreased by $18,551 USD - 37.6% of pharmacist- recommended tapers were followed by providers at the patient appointment
Lee et al., 2017	Ability of patients receiving long-term PPIs to tolerate discontinuation without gastrointestinal symptoms requiring re-initation of therapy	Quality improvement project Of the 37 residents taking PPIs for <6 months, n = 28 met discontinuation criteria Residential care facility in Ridge Meadows Hospital, Maple Ridge, British Columbia	- Pharmacist recommendation to discontinue therapy was accepted for 27 participants - 8 weeks after the intervention, 70 percent of residents were asymptomatic and did not require re-initiation of therapy
Luo et al., 2016	Assess pharmacist effect on optimizing PPI prescribing at a tertiary hospital	Retrospective observational study Electronic medical records in top ten departments with the highest PPI prescribing rates in pre-intervention and post-intervention period were exported with random computer-generated sample of n = 300	- Pharmacist interventions significantly promoted appropriate use of PPIs (44.00% versus 26.67%), decreased PPI use and reduced cost to patients from PPI therapy ($P < 0.05$)

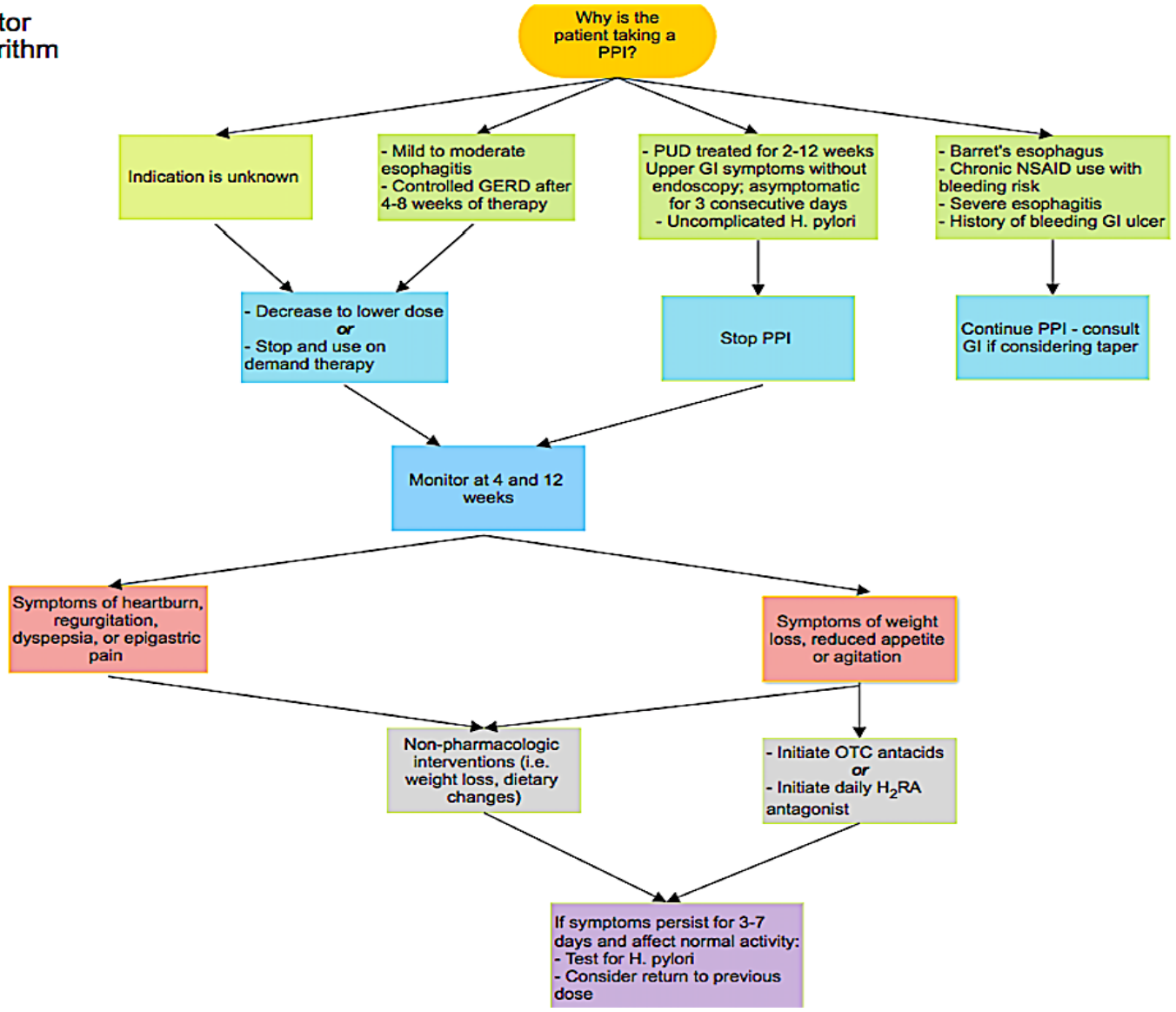
Authors & Year	Purpose	Design, Sample, & Setting	Findings
		Affiliated Hospital of Southwest Medical University in the South Sichuan Province	
McDonald et al., 2015	Reduce inappropriate PPI prescriptions through an intervention enacted during a hospitalization	Before-and-after study n = 464 consecutively admitted patients in the preintervention control group n = 640 consecutively admitted patients in the intervention group. 46–bed medical unit in a teaching hospital in Montreal, Canada.	- The proportion of PPIs discontinued at discharge increased from 7.7% per month during the pre-intervention period, to 18.5% per month postintervention (P = 0.03).
Michal, Henry, & Street, 2016	Determine effect of a pharmacist-led protocol in decreasing PPI use in non-intensive hospitalized adults	Pre-post intervention study n = 95 pre-intervention n = 94 post-intervention Single, not-for-profit community hospital in non-ICU hospitalized adults	- PPIs were discontinued in 66% of post-intervention group patients compared to 41.1% of the pre-intervention group (absolute risk reduction, 24.9%; p = 0.01)
Reeve et al., 2015	Assess the feasibility of a patient-centered deprescribing process in the adult population	Prospective feasibility study n = 57 (54.5% male; 70 ± 14yo; 14 ± 6 prescribed medications) Multidisciplinary Ambulatory Consulting Service (MACS) outpatient clinical setting at 3 different sites across South Australia	- PPI indication was considered potentially inappropriate in 44% of the sample. - 8 were suitable for trial withdrawal, and 6 consented - All 6 successfully discontinued or decreased their PPI use
Thompson et al., 2016	Assess the effect of a proton pump inhibitor deprescribing guideline on PPI usage and PPI cost	Time-series analysis n = 335 Long-term care home in Ottawa, Ontario, Canada.	- The deprescribing guideline decreased PPI usage, but the change was not statistically significant (8.7 prescriptions, 95% confidence interval [CI] 22.0 to 4.6) - The guideline significantly decreased average monthly PPI drug cost per

Authors & Year	Purpose	Design, Sample, & Setting	Findings
			resident (0.16 CAD reduction per month; 95% CI 0.29 to 0.03).
Wahking et al., 2018	Evaluate effectiveness of an PPI stewardship program in decreasing PPI use during hospitalization and upon discharge	Retrospective cohort study n = 537 admitted patients with an active outpatient PPI prescription, Internal medicine service at the Lexington Veterans Affairs Medical Center	- 41.0 percent (n = 220) of the patients did not meet criteria for continuation - 95.9 percent of these patients, (n = 211) tolerated inpatient PPI discontinuation - 3 months after discharge, 57.1 percent of patients tolerated PPI discontinuation - 3 month after discharge, 81.8 percent of patients (n = 18 of 22) tolerated PPI dose de-escalations
Walsh et al., 2016	Reduce inappropriate drug use through development and implementation of a PPI deprescribing tool and process	Prospective, descriptive quality improvement project n = 46 patients (mean age = 59 yo) Toronto Western Family Health, a primary care clinic in downtown west Toronto	- 43/46 patients on PPI therapy (93%) had their PPI reassessed, with (26%) having their PPI deprescribed

APPENDIX D:

PPI DEPRESCRIBING ALGORITHM

Proton Pump Inhibitor Deprescribing Algorithm



APPENDIX E:

DISCLOSURE FORM

PROTON PUMP INHIBITOR DEPRESCIBING ALGORITHM EDUCATION IN AN OUTPATIENT PRIMARY CARE SETTING

Kimberlie Wang

The purpose of this quality improvement project will be to implement an evidence-based algorithm and educational intervention to effectively guide primary care providers in their PPI deprescribing practices at Providence Medical Group – West Linn. The aim of this study is to determine provider attitudes towards a PPI deprescribing algorithm through qualitative surveying, and whether or not they intend to utilize the tool in their practice at Providence Medical Group – West Linn.

If you choose to take part in this project, you will be asked to listen to a five-minute PowerPoint presentation about proton pump inhibitors, and be introduced to a proton pump inhibitor deprescribing algorithm. You will also be asked to complete a brief pre- and post- intervention survey. It will take approximately five minutes to complete both surveys. There are no foreseeable risks associated with participating in this project and you will receive no immediate benefit from your participation. Survey responses are anonymous.

If you choose to participate in the project, participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw at any time from the project. In addition, you may skip any question that you choose not to answer.

For questions, concerns, or complaints about the project, you may call Kimberlie Wang, BSN, RN at 623-698-4790 or email the project chair, Jennifer Ruel, DNP, FNP-BC, ENP-BC at jruel@email.arizona.edu.

APPENDIX F:

PRESENTATION OUTLINE

Presentation Outline

Distribute stapled pre- and post- intervention surveys

Slide I: Introduction
- Title of Project
- Name of Investigator with credentials

Slide II: DNP Project
- Purpose of the Project
- Study Question

Slide III: Background on Proton Pump Inhibitors
- Clinical indications

Slide IV: Significance of the Clinical Issue
- Adverse effects

Slide V: EHR Data
- Table summarizing clinic practice on proton pump inhibitor use

Slide VI: Algorithm

Slide VII: References

Allow for time to complete post-intervention survey questions, and collect the papers

APPENDIX G:

PROVIDER PRE-INTERVENTION SURVEY

Provider Pre-Intervention Survey

1. Please circle one. I practice as a _____
   MD/DO PA NP

2. I have been practicing for
   1-5 years 6-10 years 11-15 years greater than 15 years

3. I routinely manage patients with GERD, H. pylori, peptic ulcer disease, etc.
   Strongly Disagree Disagree Neutral Agree Strongly Agree

4. My knowledge of FDA-approved PPI indications and length of therapy is at the expert level
   Strongly Disagree Disagree Neutral Agree Strongly Agree

5. I am confident in my ability to deprescribe a PPI appropriately
   Strongly Disagree Disagree Neutral Agree Strongly Agree

6. I routinely attempt to deprescribe PPI therapy in accordance with FDA recommendations for PPI use
   Strongly Disagree Disagree Neutral Agree Strongly Agree

APPENDIX H:

PROVIDER POST-INTERVENTION SURVEY

Provider Post-Intervention Survey

1. The educational session and PPI deprescribing algorithm have enhanced my knowledge of FDA-approved PPI indications, length of therapy, and deprescribing protocol
   Strongly Disagree Disagree Neutral Agree Strongly Agree

2. I believe the algorithm can encourage providers to attempt to deprescribe PPIs more frequently
   Strongly Disagree Disagree Neutral Agree Strongly Agree

3. I intend to use this algorithm to help guide my PPI deprescribing practice in the future
   Strongly Disagree Disagree Neutral Agree Strongly Agree

APPENDIX I:

THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD APPROVAL LETTER

THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

1618 E. Helen St.
P.O.Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
http://rgw.arizona.edu/compliance/home

Date:	October 03, 2019
Principal Investigator:	Kimberlie Shiow Wang
Protocol Number:	1909008050
Protocol Title:	Proton Pump Inhibitor Deprescribing Algorithm Education in an Outpatient Primary Care Setting
Determination:	Human Subjects Review not Required

Documents Reviewed Concurrently:

HSPP Forms/Correspondence: *Determination_IRB_UPDATE.pdf*

Regulatory Determinations/Comments:

- Not Research as defined by 45 CFR 46.102(l): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

APPENDIX J:

BUDGET TABLE

Budget Table

Item	Cost (USD)
Laminated algorithms	$8.11
Breakfast assortment	$10.12

REFERENCES

Al-Qaisi, M., Kahn, A., Crowell, M., Burdick, G., Vela, M., & Ramirez, F. (2018). Do recent reports about the adverse effects of proton pump inhibitors change providers' prescription practice? *Diseases of the Esophagus, 2018*(31), 1-6. doi:10.1093/dote/doy042

American Association of Colleges of Nursing. (2006). *DNP essentials.* Retrieved from https://www.aacnnursing.org/DNP/DNP-Essentials

Anderson, K., Stowasser, D., Freeman, C., & Scott, I. (2014). Prescriber barriers and enablers to minimizing potentially inappropriate medications in adults: A systematic review and thematic synthesis. *BMJ Open, 2014*(4). n.p. doi:10.1136/bmjo- pen-2014-006544

Avolio, B. & Gardner, W. (2005). Authentic leadership development: Getting to the root of positive forms of leadership. *The Leadership Quarterly, 16*(2005), 315-338. doi:10.1016/j.leaqua.2005.03.001

Avraham, O. & Biglow, M. (2018). Implementation of proton pump inhibitor deprescription protocol in geriatric residents. *Ann Pharmacother, 52*(8), 747-753. doi:10.1177/1060028018759747

Bundeff, A. & Zaiken, K. (2013). Impact of clinical pharmacists' recommendations on a proton pump inhibitor taper protocol in an ambulatory care practice. *J Manag Care Pharm, 19*(4), 325-333.

Burns, P., Rohrich, R., & Chung, K. (2011). The levels of evidence and their role in evidence-based medicine. *Plast Reconstr Surg, 128*(1), 305-310. doi:10.1097/PRS.0b013e318219c171

Centers for Medicaid & Medicare Services. (2016). *Medicare enrollment.* Retrieved from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMSProgramStatistics/2016/2016_Enrollment.html#Total%20(Fee-For-Service%20and%20Managed%20Care)%20Medicare%20Enrollment

Chambers, L. (2015). Factors for sustainability of evidence-based practice innovations: Part I. *Research and Theory for Nursing Practice, 29*(2). n.p.

Corsonello, A., Lattanzio, F., Bustacchini, S., Garasto, S., Cozza, A., Schepisi, R., Lenci, F., Luciani, F., Maggio, M. G., Ticinesi, A., Butto, V., Tagliaferri, S., & Corica, F. (2018). Adverse events of proton pump inhibitors: Potential mechanisms. *Current Drug Metabolism, 19*(2), 142-154. doi:10.2174/1389200219666171207125351

Delcher, A., Hily, S., Boureau, A. S., Chapelet, G., Berrut, G., & de Decker, L. (2015) Multimorbidities and overprescription of proton pump inhibitors in older patients. *PLoS ONE, 10*(11). n.p. doi:10.1371/ journal.pone.0141779

Eusebi, L., Rabitti, S., Artesiani, M., Gelli, D., Montagnani, M., Zagan, R., & Bazzoli, F. (2017). Proton pump inhibitors: Risks of long-term use. *Journal of Gastroenterology and Hepatology, 32*(2017), 1295-1302. doi:10.1111/jgh.13737

Farrell, B., Pottie, K., Thompson, W., Boghossian, T., Pizzola, L., Rashid, F. J., … Moayyedi, P. (2017). Deprescribing proton pump inhibitors: Evidence-based clinical practice guideline. *Canadian Family Physician Medecin de Famille Canadien*, *63*(5), 354-364.

Gagliardi, A. R., Brouwers, M. C., Palda, V. A., Lemieux-Charles, L., & Grimshaw, J. M. (2011). How can we improve guideline use? A conceptual framework of implementability. *Implement Sci*, *6*(1), 26. Retrieved from http://www.biomedcentral.com/content/pdf/1748-5908-6-26.pdf

Grol, R. P., Bosch, M. C., Hulscher, M. E., Eccles, M. P., & Wensing, M. (2007). Planning and studying improvement in patient care: The use of theoretical perspectives. *The Milbank Quarterly*, *85*(1), 93-138. doi:10.1111/j.1468-0009.2007.00478.x

Heidelbaugh, J., Goldberg, K., & Inadomi, J. (2010). Magnitude and economic effect of overuse of anti-secretory therapy in the ambulatory care setting. *Am J Manag Care, 2010*(16). 228-234.

Hiedelbaugh, J., Kim, A., Chang, R., & Walker, P. (2012). Overutilization of proton-pump inhibitors: what the clinician needs to know. *Therapy Adv Gastroenterol*, *5*(4), 219-232. doi:10.1177/1756283X12437358

Institute for Healthcare Improvement. (2019). *Medication reconciliation to prevent adverse drug effects*. Retrieved from http://www.ihi.org/Topics/ADEsMedicationReconciliation/Pages/default.asp

Kinoshita, Y., Ishimura, N., & Ishihara, S. (2018). Advantages and disadvantages of long-term proton pump inhibitor use. *Journal of Neurogastrointestinal Motility, 24*(2), 182-196. doi:10.5056/jnm18001

Koczka, C., Gerladino-Pardilla, L., & Goodman, K. (2013). Physicians' opinion of stress ulcer prophylaxis: Survey results from a large urban medical center. *Dig Dis Sci, 2013*(5), 777-781. doi:10.1007/s10620-012-2423-x

Ladd, A. M., Panagopoulos, G., Cohen, J. et al. (2014). Potential costs of inappropriate use of proton pump inhibitors. *Am J Med Sci*, 347(6), 446-451.

Lam, J., Schneider, J., Zhao, W., & Corley, D. (2013). Proton pump inhibitor and histamine 2 receptor antagonist use and vitamin B12 deficiency. *JAMA, 310*(22), 2435-2442. doi:10.1001/jama.2013.280490

Lambert, A., Lam, J., Paik, J., Ugarte-Gil, C., Drummond, M., & Crowell, T. (2015). Risk of community-acquired pneumonia with outpatient proton-pump inhibitor therapy: A systematic review and meta-analysis. *PLoS One, 10*(6). n.p. doi:10.1371/journal.pone.012800

Lee, C., Lo, A., Ubhi, K., & Milewski, M. (2017). Outcome after discontinuation of proton pump inhibitors at a residential care site: Quality improvement project. *Can J Hosp Pharm, 70*(3), 215-223.

Luo, H., Fan, Q., Xiao, S., & Chen, K. (2018). Changes in proton pump inhibitor prescribing trend over the past decade and pharmacists' effect on prescribing practice at a tertiary hospital. *BMC Health Services Research, 18*(537). n.p. doi:https://doi.org/10.1186/s12913-018-3358-5

Masclee, G., Sturkenboom, M., & Kuipers, E. (2014). A benefit-risk assessment of the use of proton pump inhibitors in the elderly. *Drugs Aging, 2014*(31), 263-282. doi:10.1007/s40266-014-0166-4

McDonald, E., Jones, J., Green, L., Jeyaraman, D., & Lee, T. (2015). Reduction of inappropriate exit prescriptions for proton pump inhibitors: A before-after study using education paired with a web-based quality-improvement tool. *Journal of Hospital Medicine, 10*(5), 281-286. doi:10.1002/jhm.2330

Michal, J., Henry, T., & Street, C. Impact of a pharmacist-driven protocol to decrease proton pump inhibitor use in non-intensive care hospitalized adults. *AM J Health-Syst Pharm, 73*(4), 126-132. doi:10.2146/ajhp150519

Nadarajan, K., Balakrishnan, T., Yee, M., & Soong, J. (2018). The attitudes and beliefs of doctors towards deprescribing medications. *Proceedings of Singapore Healthcare, 27*(1), 41-48.

Office for Human Research Protections. (2018). *Read the Belmont report*. Retrieved April 3, 2019 from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Polit, D. F. & Beck, C. T. (2012). *Nursing research: Generating and assessing evidence for nursing practice* (9th ed.). Philadelphia, PA: Wolters Kluwer Health Lippincott Williams & Wilkins.

Popovic, Z. & Thomas, J. (2017). Assessing observer variability: A user's guide. *Cardiovasc Diagn Ther, 7*(3), 3170324. doi:10.21037/cdt.2017.03.12

Providence Health & Services. (2019). *About Providence health & services*. Retrieved from https://www.providence.org/about

Rane, P., Guha, S., Chatterjee, S., & Aparasu, R. (2017). Prevalence and predictors of non-evidence based proton pump inhibitor use among elderly nursing home residents in the US. *Research in Social and Administrative Pharmacy*, *13*(2), 358-363. doi:https://doi.org/10.1016/j.sapharm.2016.02.012

Reeve, E., Andrews, J., Wiese, M., Hendrix, I., Roberts, M., & Shakib, S. (2015). Feasibility of a patient-centered deprescribing process to reduce inappropriate use of proton pump inhibitors. *Ann Pharmacother*, *49*(1), 29-38. doi:10.1177/1060028014558290

Rogers, E. M. (2003). *Diffusion of innovations*. New York: Free Press.

Rycroft-Malone, J. & Bucknall, T. (2011) *Models and frameworks for implementing evidence-based practice: Linking evidence to action*. Hoboken, NJ: Wiley-Blackwell.

Sandhu, D. S. & Fass, R. (2018). Current trends in the management of gastroesophageal reflux disease. *Gut and Liver*, *12*(1), 7-16. doi:10.5009/gnl16615

Sehested, T., Gerds, T., Fosbol, E., Hansen, P., Charlot, M., Carlson, N., Hlatky, M., Torp-Pedersen, C., & Gislason, G. (2017). Long-term use of proton pump inhibitors, dose–response relationship and associated risk of ischemic stroke and myocardial infarction. *Journal of Internal Medicine, 2018*(283), 268-281. doi:10.1111/joim.12698

Stetler, C. (2001). Updating the Stetler model of research utilization to facilitate evidence-based practice. *Nursing Outlook, 49,* 272-279. doi:10.1067/mno.2001.120517

Strand, D., Kim, D., & Peura, D. (2017). 25 years of proton pump inhibitors: A comprehensive review. *Gut Liver, 11*(1), 27-37. doi:10.5009/gnl15502

Thompson, W. & Farrell, B. (2013). Deprescribing: What is it and what does the evidence tell us? *Can J Hosp Pharm, 66*(3), 201-202.

Thompson, W., Hogel, M., Li, Y., Thavorn, K., O'Donnell, D., McCarthy, L., Dolovich, L., Black, C., & Farrell, B. (2016). Effect of a proton pump inhibitor deprescribing guideline on drug usage and costs in long-term care. *JAMDA, 17*(2016), 673-677. doi:http://dx.doi.org/10.1016/j.jamda.2016.04.020

U.S. Food and Drug Administration. (2012). *FDA approved drug products*. Retrieved from https://www.accessdata.fda.gov/scripts/cder/daf/

Wahking, R., Steele, R., Hanners, R., Lockwood, S., & Davis, K. (2018). Outcomes from a pharmacist-led proton pump inhibitor stewardship program at a single institution. *Hospital Pharmacy, 53*(1), 59-67. doi:10.1177/0018578717747192

Walsh, K., Kwan, D., Marr, P., Papoushek, C., & Lyon, W. (2016). Deprescribing in a family health team: a study of chronic proton pump inhibitor use. *J Prim Health Care, 8*(2). 164-171. doi: 10.1071/HC15946