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Deprescribing Proton Pump Inhibitors in an academic, primary care clinic: quality improvement project

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Abstract

Goals: To reduce the percentage of inappropriately prescribed proton pump inhibitors (PPIs) in patients aged 50 and older from 80% (baseline) to 60% within 12 months in an academic, internal medicine clinic.

Background: The use of PPIs has increased drastically worldwide. Internal medicine clinic patients had inappropriate use of PPIs for an average of 4–5 years.

Study: A multidisciplinary quality improvement team used the Plan-Do-Study-Act Model of health care improvement and performed a root cause analysis to identify barriers to inappropriate use of PPIs. The outcome measure was the percentage of patients inappropriately prescribed PPI. Process measures were completion rates of PPI risk assessment and esophagogastroduodenoscopy. Interventions included creation of customized electronic health record templates and education to providers and patients. Analysis was performed using monthly statistical process control charts.

Results: The average rate of PPI discontinuation was 51.1% (n=92/180), which corresponds to 30.0% inappropriate PPI usage within 12 months. The mean PPI discontinuation rate in the one-year pre-study, study and 6 months post-study period was 2.0%, 32.0% and 49.7% respectively. The mean esophagogastroduodenoscopy completion rate was 49.8% from the baseline of less than 30%.

Conclusions: We achieved a statistically significant and sustainable reduction of inappropriate PPI use to 30% from the baseline rates of 80% and surpassed our goal within 12 months. This quality improvement was unique as no pharmacy personnel were utilized in this process. The

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Ethics approval: This study was approved by the Human Subjects Institutional Review Board (HSIRB) of the University at Buffalo and was exempt from patient consent. The work was deemed a quality improvement project and not a study on human subjects.

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multifaceted strategies in a safety-net internal medicine clinic resulted in successful deprescribing of PPI and can be replicated in other setting.

Keywords

proton pump inhibitors; quality improvement; evidence-based guidelines; deprescribing PPI; primary care; inappropriate use of PPI

INTRODUCTION

Despite evidence-based guidelines proton pump inhibitor (PPI) use has increased drastically worldwide over the last 2 decades. An estimated 113 million prescriptions are filled annually in the United States (US) [1, 2]. More recently, the loss of patent protection and the availability of PPIs as generic drugs and over the counter use of PPIs has further contributed to their increasing use [3]. PPIs are the most widely prescribed class of drugs for acid-related diseases such as gastroduodenal ulcers, gastroesophageal reflux disease (GERD), Barrett's esophagus, and functional dyspepsia [4–6]. PPIs target the acid pump, H^+, K^+-adenosine triphosphatase (ATPase) to block the final step of acid secretion. PPIs have potent acid inhibition during the daytime and are effective after long-term continuous administration [7, 8]. In contrast to PPIs, Histamine$_2$-receptor antagonists (H_2RAs) are used for short-term use in the treatment of uncomplicated GERD, gastric or duodenal ulcers, gastric hypersecretion, and for mild to infrequent heartburn or indigestion [7, 9]. H_2RAs competitively bind histamine H2 receptors to inhibit gastric acid secretion. They have a quick onset, a nocturnal effect, and develop tolerance after continued use [7, 9]. H_2Ras are less potent in inhibiting acid production than PPIs, making PPIs the preferred drug for long-term usage [7–9]. There is growing concern for potential adverse effects resulting from such long-term PPI therapy [3, 10]. Studies suggests that 54.1 to 82% use of PPIs is for non-evidence-based indications [11–16]. A lack of documented ongoing indication occurs for 40% and 65% of hospitalized patients in the US and Australia [17–19] and between 40% and 55% of primary care patients in the US and the United Kingdom [20, 21]. Administration of unnecessary medication can cause adverse effects and pharmacological interactions and may lead to polypharmacy. PPI intake has been found to have a signification association with community acquired pneumonia [22, 23], *Clostridioides (Clostridium) difficile* associated diarrhea [24–26], impaired B12 absorption [27, 28], hypomagnesemia [18, 29], hip fractures [30], acute and chronic kidney disease [31] and spontaneous bacterial peritonitis in patients with cirrhotic ascites [32]. While continued use of H2RA use is associated with B12 deficiency [33], idiosyncratic cases of myelosuppression, thrombocytopenia, neutropenia, anemia, and pancytopenia [34].

The 2017 American Gastroenterological Association (AGA) guidelines recommend the following indications for PPIs usage: symptomatic GERD, acid-related complications (i.e., erosive esophagitis or peptic stricture) and Barrett's esophagus [35, 36]. PPIs are also recommended as a part of treatment regimens for eradication of H. pylori infection [37]. Furthermore, it is recommended that the dosage of long-term PPIs be periodically re-evaluated so that the lowest effective dose can be prescribed [36]. We identified a major gap in the use of AGA 2017 guidelines for prescribing PPIs in patients in the internal medicine

clinic at Erie County Medical Center. Therefore, we designed this quality improvement to reduce the rate of inappropriate PPI prescriptions from 80% (baseline) to less than 60% within 12 months. Our ultimate goal was to decrease the potential risk of adverse effects in patients and reduce overall healthcare costs.

MATERIALS AND METHODS

Setting:

A quality improvement project was conducted in an academic internal medicine clinic, located in a tertiary care safety net hospital. This clinic serves a population that is largely underprivileged, urban, uninsured and vulnerable. Patients utilize the internal medicine clinic as a longitudinal primary care clinic with approximately 700 average monthly visits with a consistent 80% show rate. Thirty-five physician residents from the University at Buffalo Internal Medicine Residency Program and four attending physicians serve this ambulatory clinic.

Design:

We used the six aims of changing the healthcare system Safe, Timely, Effective, Efficient, Equitable, and Patient-Centered model for program management [38, 39]. We designed this quality improvement based on the Plan-Do-Study-Act Cycle (PDSA) Model of health care improvement [40] and used SQUIRE 2.0 guidelines for reporting this project [41]. The multidisciplinary quality improvement team in the internal medicine clinic was comprised of attending internal medicine physicians and physician residents, patients, a social worker, nursing, administrative staff, gastroenterology physicians and information technology staff. This quality improvement team performed a root cause analysis to identify materials/ methods, provider and patient-based barriers to inappropriate use of PPIs (Figure 1). The team also utilized a driver's diagram to outline ideas for change (Table 1).

In collaboration with the information technology department, the lead physician created an electronic patient registry from electronic health records. A retrospective review of the electronic patient registry of eligible patients seen at least once within the past 12 months in the internal medicine clinic prior to the study period showed a baseline rate of 80% inappropriate use of PPI for an average of 4–5 years. Inclusion criteria included all male and female adult patients aged 50 years and older evaluated in the clinic from Jan. 2018 – Dec. 2018, on PPIs. This patient population have multiple comorbidities and had an average of six prescriptions (polypharmacy). Therefore, the team focused on this age group and not the geriatric population. Exclusion criteria included patients with a documented diagnosis of peptic ulcer disease including gastric or duodenal ulcer, Barrett's esophagus, esophagitis or NSAID/aspirin induced gastritis as evidenced by an esophagogastroduodenoscopy and chronic NSAID therapy with high risk of ulcer related bleeding.

Measurements:

The outcome measure was the percentage of patients inappropriately prescribed PPI. Process measures included PPI risk assessment during a clinic visit and esophagogastroduodenoscopy competition rates in eligible patients. Balancing measures

included potential increase in patient wait times in the clinic and poor access to esophagogastroduodenoscopy in eligible patients.

Strategy

PDSA Cycle 1: Creation of a Customized Electronic Health Record Template and Electronic Patient Registry (Jan-2018): The lead physician and information technology created a customized electronic health record template to: a) design a new workflow for nursing staff to remind providers to assess PPI use, b) document indications for continued prescribing of PPI, c) identify red flags and the need for esophagogastroduodenoscopy, d) document discussion with the patient to reduce or discontinue PPI when not indicated. This included a GERD History of Presenting Illness note template to remind physicians to evaluate for red flags and a PPI risk assessment tool to document reasons for continuation of PPI based on AGA guidelines [35, 36].

PDSA Cycle 2: Provider Education and Review of Workflow (Feb-March 2018): The physician resident team leader conducted weekly educational PowerPoint presentations in small groups for physician residents and providers. The curriculum included the 2017 AGA guidelines for prolonged PPI use, the algorithm for management of dyspepsia and strategies to deprescribe PPI when not indicated. Pre and post presentation tests, comprised of five multiple choice questions, were performed to assess knowledge. The lead physician also reviewed the changes in electronic health record workflow with the nursing staff and providers.

PDSA Cycle 3: PPI Risk Assessment Tool and Medication Reconciliation (April- July 2018): During this PDSA cycle, providers focused on addressing GERD symptoms and completing medication reconciliation for all patients including hospital discharge visits. Team leaders encouraged providers to complete the PPI risk assessment tool in the electronic health record. This was crucial to capture data in the patient electronic registry. Refresher training was given to physician residents and initial training was provided to new interns.

PDSA Cycle 4: Patient Education and Feedback to Stakeholders (Aug-Oct 2018): The nursing staff and internal medicine clinic physician residents provided patient education about potential adverse effects of prolonged PPI use. The physician resident team leader developed pamphlets for patient education regarding side effects and appropriate risk reduction strategies for GERD. The lead physician and physician resident team leader continued to provide progress reports to the quality improvement team and received feedback for possible interventions.

PDSA Cycle 5: Pocket Guides for Providers and Follow up of Patients after PPI Discontinuation (Nov–Dec 2018): The physician resident team leader created pocket cards for providers that outlined the algorithm for dyspepsia management and potential side effects of prolonged PPI use. Providers continued to follow up with patients after PPI discontinuation to evaluate rebound symptoms.

Data Analyses.

We used quality improvement macros software to plot monthly statistical process control charts for outcome, process and balanced measures. X-mR (moving range) chart was used to track monthly average wait times.

RESULTS

Demographics:

201 patients were on PPIs at some time during clinic visits within the 12-month study period. This population had a mean age of 62.4, was 47.8% female, 62.8% were African Americans, 26.7% were White while 10.5% were classified as other race. 21 patients were found to have a valid indication for PPI use and were excluded from the intervention group.

Outcome measures

a) PPI discontinuation rate: The average rate of PPI discontinuation was 51.1% (unique patients: n = 92/180) resulting in 30% inappropriate chronic PPI use from a baseline of 80% within 12 months. The mean of the PPI discontinuation rate in the pre-study one-year baseline period was 2.0%, in the one-year study period was 32.0% and in the 6 months post study period was sustainable at 49.7% (Figure 2a). We observed stability of the process of PPI discontinuation rates during the pre-study one-year period (Figure 2a). We observed monthly sustainable variations with a mean of 32.0% in discontinuation of PPI. We achieved a statistically significant improvement in the percentage of PPI discontinuation (Figure 2a).

b) Health care utilization results: A direct cost savings of $13,992 occurred annually from PPI discontinuation. Ninety-two patients were affected; 11 patients were on 40mg esomeprazole ($26 for 30 d), 14 patients were on omeprazole ($15 for 30 d), and 67 patients were on pantoprazole ($10 for 30 d) [42]. Patients were de-prescribed PPIs, assuming full compliance by the patient and a constant prescription rate, an annual cost of $13,992 ($3432 + $2520 + $8040) occurred.

Process measures

a) Esophagogastroduodenoscopy completion rates: The completion rate mean in patients on long term PPI use was 49.8% (Figure 2b). The baseline completion rate was estimated at less than 30%. There were 25 completed during the 12-month study period. Six patients had normal findings. Abnormal findings included peptic ulcer disease (n=7), esophagitis (n=8), gastritis/erosions (n=9), hiatal hernia (n=4), AV malformations (n=1) and other results included esophageal stricture, gastric/esophageal polyp, esophageal varices, Schatzki’s ring, benign polyps, lymphoid aggregates, gastric wall thickening and melanosis duodenitis (n=7). The same patient may have had multiple findings on esophagogastroduodenoscopy.

b) PPI risk assessment completion rates: PPI risk assessment was documented as structured data in 15.6% of patients. The majority of patients had their GERD symptoms assessed during the study period, however, this was not documented as a structured data field

in the electronic health record to capture in the patient registry. This was based on evidence of sustainable reduction in PPI discontinuation rate.

Balance measures

a) Patient wait time: The average wait time (time spent in in the examination room for nursing and provider's assessment) was 42.62 minutes during the study period and 44.66 minutes during the pre-study one-year period for unique patients. The average wait time was 42.74 minutes, with an upper control limit (UCL) of 49.40 and a lower control limit (LCL) of 36.09.

b) Access to esophagogastroduodenoscopy: Due to an increase in referrals for esophagogastroduodenoscopy and lack of sufficient gastroenterology providers, there was an increase in the wait time from about two months to four months during this quality improvement project.

DISCUSSION

Several initiatives have had relatively positive success in reducing the use of PPIs in different healthcare settings, with many of these studies including pharmacy personnel to identify inappropriate prescriptions [43–49]. In a Tennessee outpatient internal medicine clinic, a protocol was developed that utilized a clinical pharmacist and an internal medicine physician to adjust PPI usage. More than one-half of patients were successfully stepped down to H_2RAs [44]. In a residential care facility, a pharmacist identified residents with the criteria for PPI discontinuation and recommended discontinuation of therapy. Eight weeks post intervention, 70% of residents that discontinued PPI were asymptomatic and did not require re-initiation of medications [48]. In the current quality improvement project, providers tapered and discontinued PPI in patients who did not have a clear indication for the use, they were either switched to H_2RAs or were taken off the PPI medication. Patients on long term PPI were also referred to gastroenterology services for esophagogastroduodenoscopy when indicated. Patients were continued on PPI that had evidence of peptic ulcer disease, esophagitis, esophageal ulceration, gastritis or gastric erosions on esophagogastroduodenoscopy. A limited number of patients had rebound symptoms after PPI discontinuation, symptoms were managed with H_2RAs. This quality improvement was unique as no pharmacy personnel were utilized to identify inappropriate prescriptions.

The success of this quality improvement project was attributed to provider education, changes in electronic health record templates, patient education and engagement, and team work. Previous studies, occurring in multiple settings including hospitals and primary care, have yielded mixed results using education as an intervention to reduce inappropriate PPIs prescriptions [21, 47, 50]. A simple physician educational intervention was unsuccessful in reducing PPI usage in a primary care setting [21], however education to the internal medicine clinic providers and nursing staff was successful in helping to reduce inappropriate PPI prescriptions in this quality improvement. Patients were actively engaged in this quality improvement project through education, identification of barriers to discontinuation of inappropriately prescribed PPIs, shared decision making and feedback on various challenges

that contributed to the discontinuation of PPIs. Erie County Medical Center administrative and nursing leadership were actively engaged in this project, allocating nursing time for education and information technology resources to create innovative electronic health record templates.

Barriers included lack of pharmacy personnel in the clinic due to limited resources in a hospital-based safety net clinic. Providers demonstrated suboptimal use of the PPI risk assessment tool to capture structured data in electronic health record. This was attributed to time constraint barriers for providers during a clinic visit while addressing patient's needs in a patient population with multiple comorbidities. This tool required an extra step after discontinuation of PPI as a manual entry in electronic health record, therefore providers were unable to complete this tool. We were unable to implement a work flow for the pre-visit planning by nursing staff to identify high risk patients that require esophagogastroduodenoscopy, due to lack of resources.

This study had several limitations. This quality improvement was performed in a safety-net primary care clinic in patients with multiple comorbidities, so the results may not be generalizable to other settings. The results of this project should be interpreted with caution. PPIs are available over the counter without a provider prescription in US, making it difficult to determine if patients were adherent to discontinuation of PPI prescriptions. The majority of patients in a safety-net clinic were unable to pay for the cost of over the counter PPIs and patients didn't mention their use to providers during clinic visits. Based on this information, it may be possible that patients were not using over the counter PPIs after prescriptions were discontinued.

Overall, a successful strategy was implemented to improve prescribing PPIs with multiple implications affecting patient care, polypharmacy, reducing adverse drug reactions and drug interactions while also reducing cost utilization in a primary care setting. No pharmacy personnel were utilized to identify inappropriate prescriptions which is makes this quality improvement was unique. This study exceeded the goal to deprescribe PPI within a short period of time and was able to sustain the changes. We achieved a statistically significant reduction in inappropriate PPI use to 30% from the baseline rates of 80% and surpassed goal within 12 months. We sustained PPI discontinuation rates at 49.7% during the 6-month post-project period (January-June 2019). Processes and workflows designed in this quality improvement project for deprescribing PPI in the internal medicine clinic have become the standard of care and a part of a routine clinic visit. The multifaceted strategies in a safety-net internal medicine clinic resulted in successful deprescribing of PPI and can be replicated in other setting to address gaps in AGA guidelines for chronic PPI use.

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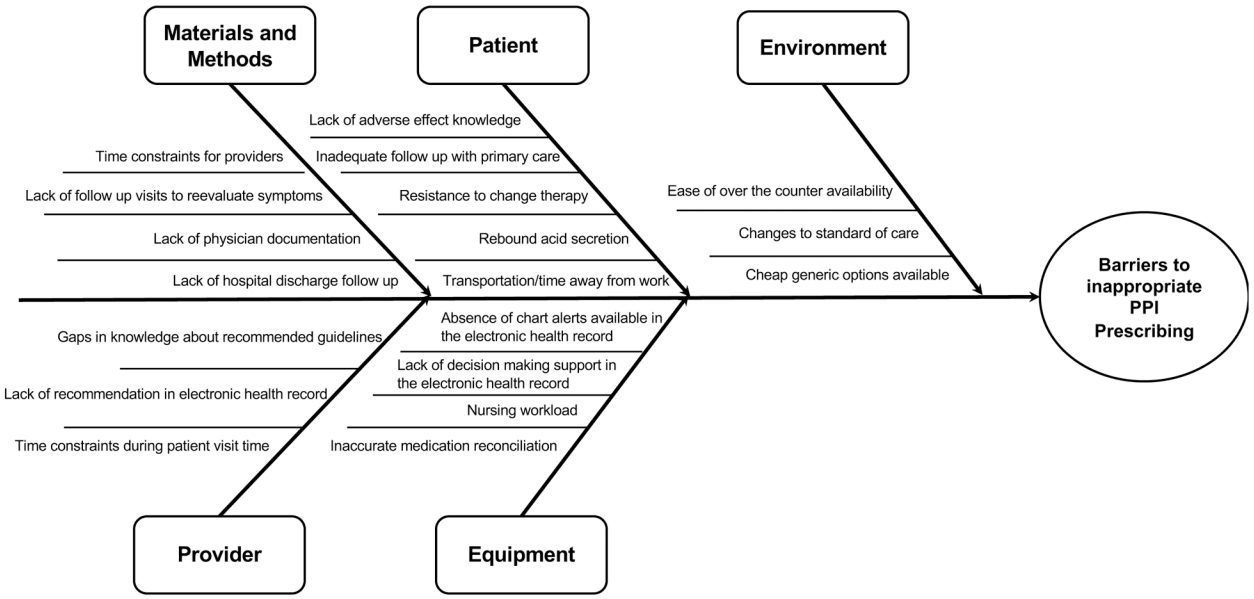

Figure 1.

Fishbone diagram – Root cause analysis identifying barriers to appropriate PPI prescribing practices.

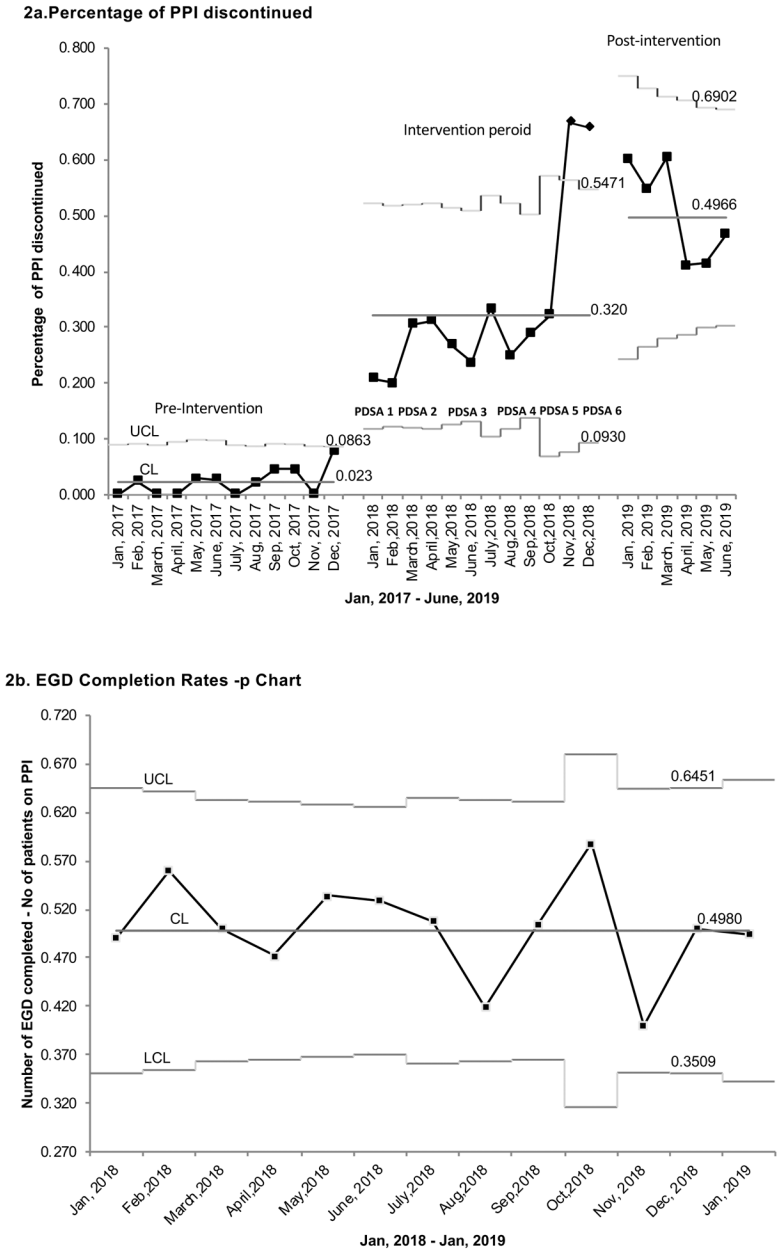

Figure 2.

Outcomes measures 2a) p chart for Percentage of PPI discontinuation, 2b) Esophagogastroduodenoscopy Completion Rates - p Chart

Table 1.

Driver Diagram for PPI prescription

Primary Driver	Secondary Driver
Organizational Alignment	• Engage administration including executive leadership and stakeholders • Align with other organizational initiatives • Create consensus among stakeholders for chronic use of PPI
Team Building	• Create algorithm for accurate diagnosis, develop protocol and integrate into nursing and physician workflow • Provide education and training to physicians, staff and patients • Partner with gastroenterology staff, physicians and information technology staff • Foster culture of collaboration and team work • Engage residents to implement PPI quality improvement project
Leverage health information technology	• Create structured data capturing and accurate history in electronic health record and patient database for population health • Develop outreach programs to track patients who are lost to follow up • Create and integrate customized template in electronic health record to remind physicians to evaluate chronic PPI use • Create electronic health record database of eligible patients and share reports to residents and attending physicians to identify patients on chronic PPI • Build new workflow and template in electronic health record to improve efficiency • Identify eligible patients by nursing during pre-visit planning • Identify high risk patients that require esophagogastroduodenoscopy • Train residents and physicians to optimize accurate use of PPI and identify red flags that require attention
Patient Engagement	• Engage patients and get feedback on processes and promote shared decision • Know the patient related barriers to discontinuation of inappropriate PPI • Overcome identified barriers to discontinue inappropriate PPI use • Create awareness about complications of chronic PPI use to patients and family
Close loops for referrals & tests	• Implement care coordination between internal medicine clinical and gastroenterology staff for scheduling for ordering, scheduling and completion of esophagogastroduodenoscopy • Ensure timely access for gastroenterology clinic and improve capacity • Implement new workflow to improve no-shows or failure to schedule for esophagogastroduodenoscopy • Establish protocol to notify patients in a timely manner about esophagogastroduodenoscopy results and follow-up in clinic