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Deprescribing Proton Pump Inhibitors in a Rural Health Clinic

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March 18th, 2024

Abstract

Background: Proton pump inhibitors (PPIs) have been extensively prescribed for gastrointestinal pathologies, contributing to \$14 billion in annual expenditure in the United States alone. Inappropriate PPI prescriptions, affecting 48% of adults, raise concerns about prolonged usage and associated health risks. Addressing these issues is vital, considering the significant impact of PPIs on patient health and healthcare costs.

Local Problem: A Midwestern clinic grapples with inappropriate and unnecessary PPI use among patients. In response, a comprehensive deprescribing intervention combining a provider algorithm with patient education was implemented to reduce PPI usage that was medically unnecessary.

Methods: A literature review spanning 2016 to 2023 identified key themes and characteristics related to PPI deprescribing. Barriers and facilitators were analyzed, and an organizational assessment informed targeted intervention. The Health Promotion Model and Six Sigma model guided project implementation, including data collection, medication reconciliation and providerled deprescribing decisions.

Interventions: The deprescribing approach integrated a provider algorithm and patient education materials. Medical Assistants identified PPI users, and Primary Care Providers (PCPs) utilized a deprescribing algorithm to guide tapering or discontinuation. Eligible patients received educational handouts outlining risks, benefits, and lifestyle modifications.

Results: Of the 35 initially targeted patients, 33 were included, with a 72.7% success rate in PPI deprescription. Statistical analysis using the Agresti-Coull test demonstrated a significant reduction in PPI use, with a confidence interval of 55.61% to 85.1%.

Conclusion: The study achieved a statistically significant reduction in PPI use, highlighting the potential impact of tailored deprescribing interventions. The success of the deprescribing algorithm emphasizes the significance of evidence-based decision support for PCPs.

Implications: PCPs play a pivotal role in fostering patient understanding and adherence to deprescribing regimens. The success of the deprescribing algorithm reinforces the importance of evidence-based decision-support tools for PCPs, contributing to optimized PPI practices in primary care settings.

Background

Over the past four decades, proton pump inhibitors (PPIs) have been widely prescribed for a diverse range of gastrointestinal pathologies, demonstrating their effectiveness in reducing excessive acid production in the stomach (Avraham & Biglow, 2018). The widespread utilization of PPIs in the United States alone contributes to an annual expenditure of 14 billion dollars (Nguyen-Soenen et al., 2022).

Approximately 48% of adults receive inappropriate PPI prescriptions, indicating potential lapses in prescribing practices, with additional concerns regarding prolonged usage beyond approved durations (Avraham & Biglow, 2018; Lai et al., 2021). Many patients lack knowledge of the long-term effects of PPIs and may be hesitant to discontinue PPI therapy due to the perceived benefits (Song, Zu & Lu, 2014). While PPIs offer short-term benefits, prolonged use has been associated with polypharmacy and various health concerns. Including reduced levels of essential nutrients and increased risks of bone fractures, pneumonia, dementia, and intestinal infections, such as Clostridium difficile (Lai et al., 2021). The significance of these risks emphasizes the need for primary care providers (PCPs) to implement appropriate deprescribing methods. As PCPs play a crucial role in the well-being of their patient population, it becomes essential for PCPs to educate patients about the potential risks associated with PPI use and initiate appropriate deprescribing.

Deprescribing, highlighted by Avraham and Biglow (2018), is a crucial component of responsible prescribing practices, involving actions like adding, initiating, changing, switching, titrating, tapering, or discontinuing medication therapy. However, patients often encounter challenges in adhering to deprescribing PPIs as they experience immediate symptom relief while taking these medications (Farrell et al., 2017). Over-the-counter availability of PPIs since 2003,

contributes to the initiation of therapy without consulting a primary care physician, exacerbating the estimated 113 million annual prescriptions, and potentially leading to inappropriate and prolonged use (Calvo et al., 2021). Inappropriate PPI use is further fueled by the accessibility of generic drugs (Nallapeta et al., 2020; Hayes et al., 2019). Alarming statistics from the American Gastroenterological Association (AGA) reveal that more than 25% of patients prescribed PPIs continue using them without medical indication, highlighting the need for primary care physicians to carefully review the ongoing indications for PPI use (Targownik et al., 2022). A lack of documented ongoing indication is observed in 40% to 55% of primary care patients, revealing insufficient adherence to the annually updated evidence-based practice guidelines by the American Gastroenterological Association among both patients and providers (Nallapeta et al., 2020).

Methods

Purpose of Project

The purpose of this project was to address the issue of inappropriate and unnecessary proton pump inhibitor (PPI) use among patients at a clinic in the Midwest. The goal was to implement a comprehensive deprescribing intervention that combines a provider deprescribing algorithm with patient education to reduce PPI usage when it is no longer medically indicated.

Literature Review

A comprehensive literature search from 2016 to 2023 on Google Scholar, CINAHL, and PubMed, using key terms like "PPI," "deprescribing protocol," and "polypharmacy," resulted in 186 articles initially being retrieved. After applying inclusion/exclusion criteria and Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, 11 relevant

articles underwent critical appraisal. The final review included seven articles, comprising three systematic reviews and four prospective studies.

Identified Themes and Characteristics

A comprehensive analysis of the articles revealed several common themes. These themes included the effects of long-term PPI use, adherence to deprescribing PPIs, identification of treatment gaps, perceived barriers, and successful educational interventions. The sample sizes varied significantly, encompassing both small and large national studies. Most of the articles utilized the American Gastroenterological Association (AGA) recommended clinical practice updates as the standard of care. However, there is a lack of real-world guidelines and decision support aids specifically for deprescribing. The primary care practice setting emerged as the most common context identified across the articles. Four articles examined educational interventions for deprescribing, two articles assessed the prolonged use of PPIs, and one article evaluated clinical practice guidelines for a decision-support algorithm.

Barriers. The analyzed articles highlighted key barriers to deprescribing, including inadequate healthcare provider motivation, time constraints during appointments, patient resistance, and limited awareness of the risks associated with long-term PPI use (Calvo et al., 2021; Nallapeta et al., 2020; Farrell et al., 2017). These barriers are crucial considerations for the project, guiding the development of targeted deprescribing interventions.

Facilitators. The analysis highlighted facilitators essential for the project, emphasizing the importance of staying updated on PPI guidelines, conducting medication reviews, providing patient education, engaging in shared decision-making, and promoting health (Farrell et al., 2017; Walsh et al., 2016; Calvo et al., 2021). These insights not only inform the development of

participant-engagement strategies but also shape the direction of targeted deprescribing interventions, underscoring the pivotal role of these facilitators in optimizing patient care.

Provider adherence. Implementing a PPI deprescribing algorithm is crucial for reducing long-term complications (Calvo et al., 2021; Nguyen-Soenen et al., 2019) however, the lack of specific guidelines for PCPs highlights a critical gap in clinical practice (Farrell et al., 2017; Nguyen-Soenen et al., 2019). To ensure effective implementation, provider adherence is key, and the use of algorithmic or graphical tools enhances guideline adoption (Calvo et al., 2021; Nguyen-Soenen et al., 2019). Establishing a robust patient-provider relationship, along with regular education, training, and staff support, contributes to improved patient safety and minimizes risks associated with long-term PPI use (Farrell et al., 2017).

Implications of non-adherence. Despite existing guidelines and best practice advice statements for PPI deprescribing in dyspepsia by the AGA, provider adherence is challenging due to the algorithm's complexity (Calvo et al., 2021; Nallapeta et al., 2020). Nonadherence increases the risk of unnecessary PPI use, contributing to side effects, and stems from factors such as lack of awareness and time constraints during clinical encounters (Farrell et al., 2017; Kulkarni et al., 2021; Wilsdon et al., 2017). Overcoming these barriers necessitates continuous training, support, and culture of evidence-based medicine, enhancing provider adherence to deprescribing practices and improving patient safety and care quality (Walsh et al., 2016).

Process Change

The QI project implemented a comprehensive PPI deprescribing approach, integrating a provider algorithm with patient education. The structured algorithm facilitated tailored PPI reduction, and patient education played a pivotal role, in fostering awareness and commitment, resulting in reduced consumption. Strategies from Deprescribing.org, including the PPI

deprescribing algorithm and patient education leaflets, proved effective in aiding providers and empowering patients (Calvo et al., 2021; Farrell et al., 2017; Nguyen-Soenen et al., 2019; Kulkarni et al., 2021; Nallapeta et al., 2020; Walsh et al., 2016; Wilsdon et al., 2017).

Organizational Assessment

The family medicine clinic, situated in a rural Midwestern community, aligned with a mid-sized nonprofit hospital and larger healthcare system, aimed to establish a PPI deprescribing program. Utilizing the McKinsey 7S Model, the organizational assessment scrutinized crucial elements to address challenges related to inappropriate PPI use. Stakeholder interviews with leaders and PCPs provided insights into strengths, such as a dedicated healthcare team, commitment to patient outcomes, and external resources. Weaknesses included EMR integration challenges, paper-based documentation, staff knowledge gaps, limited time, patient noncompliance, and OTC availability of PPIs. These insights guided targeted interventions to optimize PPI practices and enhance patient education on associated risks.

Stakeholders

The success of the deprescribing project hinged on the collaboration of key stakeholders, with patients as the primary beneficiaries. Patients played a vital role in the deprescribing process, requiring active engagement and understanding. Their informed participation enhanced adherence to the deprescribing strategy, and their feedback provided valuable insights for assessing the project's effectiveness.

PCPs were central figures in the project, their responsibilities included assessing patients' medication needs and implementing the deprescribing algorithm. The clinical judgment and expertise of PCPs were pivotal in determining the appropriateness of deprescribing PPIs for individual patients. Additionally, effective communication with patients about the deprescribing

process was essential, bridging the gap between evidence-based guidelines and personalized patient care.

Support staff, often the initial point of contact for patients in a clinical setting, played a critical role in the project's early stages. Their involvement in the medication review process was key to identifying patients currently using PPIs. Serving as a vital link between patients and PCPs, support staff helped initiate the deprescribing process by updating health records and facilitating the use of the proposed algorithm. The ability of the clinical support staff to correctly identify which patients were on PPIs ensured that the right individuals were considered for deprescribing.

Leadership within the healthcare organization was instrumental in overseeing project implementation. Directors and managers contributed by identifying current evidence-based research to establish policies and procedures that guided PCPs. The leadership's role in allocating resources, supporting infrastructure, and coordinating communication among different departments was crucial. Managing logistical challenges during the project's execution fell under the purview of leadership, highlighting their pivotal support for the seamless integration of the deprescribing intervention into the clinic's workflow.

Conceptual Model

To guide this project, the Health Promotion Model (HPM) developed by Nola J. Pender in 1982 was chosen as a framework. This midrange theory emphasizes the crucial relationship between PCPs and patients, highlighting the active role of patients in health-promoting behaviors and considering environmental influences (Aqtam & Darawwad, 2018). The HPM's focus on individual factors aligned seamlessly with the project's goals, offering insight into the intricate interplay between patients' perceptions, knowledge, and motivations regarding PPI usage. This

understanding formed the foundation for tailored, patient-centered interventions. The HPM's emphasis on self-efficacy and perceived benefits informed education initiatives designed not only for information dissemination but also to empower patients with a comprehensive understanding of PPI deprescribing, facilitating informed decision-making about their medication regimens.

Implementation Framework

The Six Sigma model, recognized for its systematic and data-driven approach to enhancing healthcare processes and quality, was employed as the implementation framework for this project (McEwen, 2018). Operating through the Define, Measure, Analyze, Improve, and Control (DMAIC) cycle, the model provided a structured approach to identify, analyze, and improve the deprescribing process for PPIs. In the "Define" phase, the deprescribing issue scope was determined, patient needs were assessed, and specific goals were established. The "Measure" phase involved collecting data on PPI usage, patient profiles, and prescribing reasons. Root cause analysis in the "Analyze" phase informed the identification of a tailored deprescribing algorithm. The "Improve" phase included clear guidelines, communication protocols, and patient education materials. The "Control" phase ensured sustained improvements through continuous monitoring and addressing emerging issues. This model supported project objectives and the establishment of effective, patient-centered deprescribing practices, ultimately leading to improved outcomes.

Data Collection

The initiative began with Medical Assistants (MAs) conducting medication reconciliation and identifying patients on proton pump inhibitors (PPIs). MAs initiated the PPI deprescribing

information sheet for PPI users and handed it to the PCPs for plan completion. PCPs utilized the Deprescribing.org algorithm (Appendix A) to guide safe PPI tapering or discontinuation decisions. Eligible patients received a Deprescribing.org patient education handout (Appendix B) outlining risks, benefits, and lifestyle modifications. Documentation involved securely placing completed PPI deprescribing information sheets in patient records. Follow-up calls assessed PPI usage status, with results documented on the sheets for comprehensive patient progress tracking. Permission was obtained from Deprescribing.org to utilize the algorithm and patient education materials for the study, ensuring compliance with ethical and legal considerations.

Data Management

Follow-up call data was aggregated for confidentiality, maintaining patient information sheets until data confirmation post-two-week follow-up. Patient identifiers were meticulously removed before transferring data to Excel, ensuring anonymity and privacy protection. An organized Excel spreadsheet served as the primary tool for collecting and organizing information, providing a structured format for analysis while safeguarding data accuracy and patient confidentiality.

Data Analysis

Inclusion criteria for the analysis included all male and female adult patients aged 18 years and older who were evaluated in the clinic from December 15th, 2023, to February 16th, 2024, and were on PPIs. The analysis plan focused on assessing PPI deprescription effectiveness through bar charts representing the binary outcome of successful or unsuccessful deprescribing. A pie chart detailed reasons for non-adherence. A sample size of 30 patients ensured statistical power, and the Agresti-Coull test assessed the intervention's impact on PPI use. Qualitative data analysis coded patient responses to gain insights into reasons for not deprescribing, contributing

to a comprehensive patient-centered approach. Statistical analyses were conducted in collaboration with a statistics graduate student for validity and appropriateness.

Results

In the implementation phase of the study aimed at assessing PPI deprescribing effectiveness, careful consideration was given to a sample size of 35 patients, although statistical power analysis recommended only 30 patients for significance. However, due to the availability of 35 patients within the project's timeframe, this larger sample size was utilized. Unfortunately, two patients were excluded due to the inability to establish contact during the 2-week follow-up, resulting in a final inclusion sample size of 33 patients. Drawing from prior studies by Odenthal et al. (2020), which indicated a range of 31% to 66% in PPI deprescribing rates using different interventions within primary care settings, the research objectives were thoughtfully formulated with a targeted PPI discontinuation rate of 49%, which is the median of these percentages. This approach helps mitigate the impact of outliers and ensures a balanced approach to reducing PPI usage. This strategic alignment positioned the study within the broader context of existing literature, contributing meaningfully to the discourse surrounding PPI discontinuation rates in primary care settings.

The analysis plan employed bar charts (Appendix C) to depict binary outcomes regarding the success of PPI deprescribing among the included 33 patients. Notably, 72.7% successfully underwent PPI deprescription, while 27.3% did not adhere to the regimen. A detailed pie chart (Appendix D) delved into qualitative insights gained from patient responses, identifying key barriers to deprescribing. Symptom persistence was reported by 33.33% of non-adherent patients, while concerns about symptoms returning and a lack of understanding accounted for 22.22% and 44.44%, respectively. These nuanced findings contribute to a holistic understanding

of PPI deprescribing challenges, emphasizing the significance of a patient-centered approach in clinical interventions.

Collaborating with a statistics graduate student, we utilized the Agresti-Coull test (Appendix E) to assess the statistical significance of the intervention. The results, presented with 95% confidence, unequivocally demonstrated a statistically significant reduction in PPI use among patients for whom PPI was no longer indicated. The precision of these findings is underscored by the 95% confidence interval, revealing that between 55.61% and 85.1% of individuals in the population have undergone PPI deprescription. This demonstrates a significant reduction in PPI use, highlighting the impact of the intervention.

Discussion

Outcomes of the PPI deprescribing intervention, as evidenced by a 72.7% success rate among the targeted 33 patients, provide valuable insights into addressing inappropriate PPI use. The commendable success rate underlines the potential impact of tailored deprescribing interventions in a primary care setting. The 27.3% non-adherence rate, however, sheds light on persistent challenges, necessitating a closer examination of barriers to inform future interventions. The qualitative analysis of patient responses revealed nuanced factors contributing to non-adherence, such as symptom persistence, concerns about symptom recurrence, and a lack of understanding.

Implications for Practice

The findings underscore the pivotal role of PCPs in fostering patient understanding and adherence to deprescribing regimens. The identified barriers emphasize the need for nuanced patient education strategies that address concerns about symptoms and improve overall patient engagement. The success of the deprescribing algorithm, as evidenced by the statistically

significant reduction in PPI use, reinforces the importance of evidence-based decision-support tools for PCPs. These tools can enhance deprescribing practices and contribute to optimizing PPI practices in primary care settings.

Financial Impact

The project's utilization of CPT add-on code 99212 was instrumental in achieving notable financial gains for the organization. Specifically, by incorporating this code, the project contributed to an overall revenue increase of \$1,533 for the 33 patients seen. This code, typically utilized for established patient visits involving straightforward medical decision-making or a total encounter time of 10–19 minutes, proved an effective tool in enhancing revenue generation.

Furthermore, beyond the direct financial impact on the organization, the project's focus on deprescribing PPIs also holds significant cost-saving implications for patients. Given that a typical month's supply of PPI medication costs patients approximately \$30, the initiative to deprescribe these medications not only contribute to improved patient care but also alleviates financial burdens on individuals seeking treatment. This dual approach underscores the project's commitment to both fiscal responsibility and patient-centered care, ultimately yielding comprehensive benefits for all stakeholders involved.

Limitations

Several limitations merit consideration. The modest sample size of 33 patients, though carefully selected, may not fully capture the diversity of patient responses to deprescription efforts, potentially limiting the generalizability of the findings. Excluding two patients due to communication challenges introduces a potential source of bias, emphasizing the need for robust communication strategies in future studies. Time constraints and staffing challenges affected data collection efficiency, influencing the depth of qualitative insights. The absence of an Electronic

Health Record (EHR) system highlighted the crucial role of integrated technology in optimizing research logistics. Beyond these primary limitations, challenges related to patient heterogeneity and varied healthcare settings further underscore the need for larger, multicenter studies.

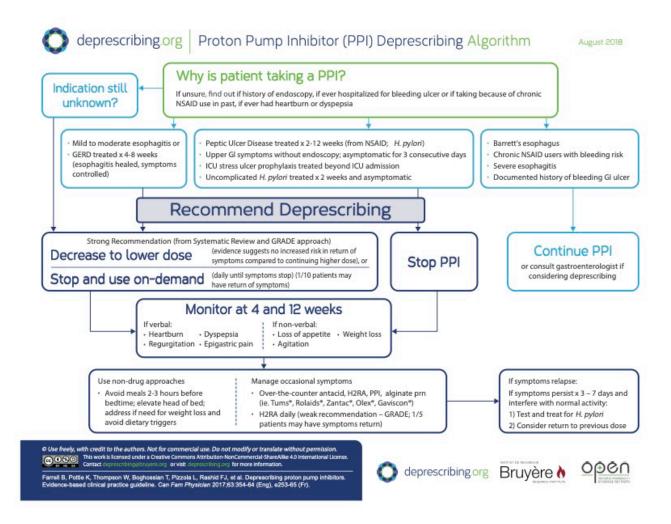
Sustainability

To ensure the sustained impact of the deprescribing intervention, addressing these limitations is imperative. Ongoing provider education, with an emphasis on time-efficient strategies, can enhance the feasibility of similar projects. Future studies should consider EHR integration and explore strategies to mitigate staffing challenges, fostering a more streamlined implementation process. Long-term integration into routine clinical workflows, continuous education, transition to EHR, and dissemination of project outcomes are crucial components for the sustained success of deprescribing initiatives. Part of the sustainability plan of the project involves disseminating the project's outcomes to motivate and guide future changes in other PCP offices.

Conclusion

This study represents a significant step toward addressing the challenges associated with inappropriate PPI use in the primary care setting. The statistically significant reduction in PPI use, coupled with insights into barriers and facilitators, provides a foundation for refining deprescribing strategies. By comprehending patient-specific challenges and implementing tailored interventions, PCPs play a pivotal role in advancing PPI deprescribing practices, contributing to enhanced patient safety and care quality. Ongoing research and collaborative efforts remain imperative for the continual evolution and refinement of deprescribing strategies in various healthcare contexts.

Appendix A



Appendix B



deprescribing.org | Is a Proton Pump Inhibitor still needed?

August 2018

What are Proton Pump Inhibitors (PPIs)?

Proton Pump Inhibitors, or PPIs, are a class of drugs that are used to treat problems such as heartburn or stomach ulcers.

There are many different types of PPI drugs:

- · Lansoprazole (Prevacid *)
- Omeprazole (Losec*)
 Pantoprazole (Tecta*, Pantoloc*)
- Rabeprazole (Pariet *)
 Esomeprazole (Nexium *)
- Dexlansoprazole (Dexilant*)
 Omeprazole (Olex*)

Why use less of, or stop using a Proton Pump Inhibitor?

While PPIs are effective at treating many stomach problems, such as heartburn, they are often only needed for a short period of time

Despite this, many people take PPIs for longer than they may need.

Research shows that for some people, doses can be safely lowered or the drug used just when needed for symptom relief.

PPIs are generally a safe group of medications; however, they can cause headache, nausea, diarrhea and rash. They may also increase risk of:

- Low vitamin B12 and magnesium blood levels
- Bone fractures
- Pneumonia
- · Intestinal infections such as C. difficile

Stopping a Proton Pump Inhibitor is not for everyone

Some people need to stay on a PPI for a long time. However, others only need this medication for a short period of time

When the ongoing reason for using a PPI is unclear, the risk of side effects may outweigh the chance of benefit.

People who should continue on a PPI include those with any of the following:

- Barrett's esophagus
- Long-term use of nonsteroidal anti-inflammatory drug (e.g. Advil*)
- Severe inflammation of the esophagus
 Documented history of bleeding stomach ulcer

How to safely reduce a Proton Pump Inhibitor

People over the age of 18 who have been taking a PPI for more than 4 to 8 weeks should talk to a doctor, nurse practitioner or pharmacist about whether stopping a PPI is the right choice for them.

Doctors, nurse practitioners or pharmacists can help to decide on the best approach to using less of a PPI. They can advise on how to reduce the dose, whether to stop it altogether, or how to make lifestyle changes that can prevent heartburn symptoms from returning.

Reducing the dose might involve taking the PPI once daily instead of twice daily, lowering the number of mg (e.g. from 30mg to 15mg, or 40mg to 20mg, or 20mg to 10mg depending on the drug), or taking the PPI every second day for some time before stopping.









deprescribing.org | Is a Proton Pump Inhibitor still needed?

August 2018

What to monitor after reducing a Proton Pump Inhibitor

After reducing or stopping a PPI with the help of a physician, nurse practitioner or pharmacist, it is important to check for, and report signs of:

- Heartburn
- Reflux
- Stomach pain

If the patient is not able to speak, check for, and report signs of:

- Loss of appetite
- Weight loss
- Agitation

Other ways to reduce heartburn, reflux or stomach pain

Lifestyle changes:

- Avoid triggers (e.g. coffee, alcohol, spicy foods, chocolate)
- Avoid food 2-3 hours before bedtime
 Elevate the head of the bed
- Lose weight

Manage occasional heartburn with over the counter drugs such as:

- Tums
- Zantac
- Gaviscon

What to do if stomach problems continue

If heartburn, reflux, or stomach pain continues after 3-7 days and interferes with normal activities, please talk to a doctor, nurse practitioner or pharmacist. They can help decide whether to return to a previous PPI dose or whether to use the PPI 'on-demand' (daily until your symptoms stop). They may also suggest a test for a treatable condition called *H. pylori*.

Personalized PPI dose reduction strategy:

This pamphlet accompanies a deprescribing guideline and rithm that can be used by doctors, nurse practitioners, or pharmacists to guide deprescribing.

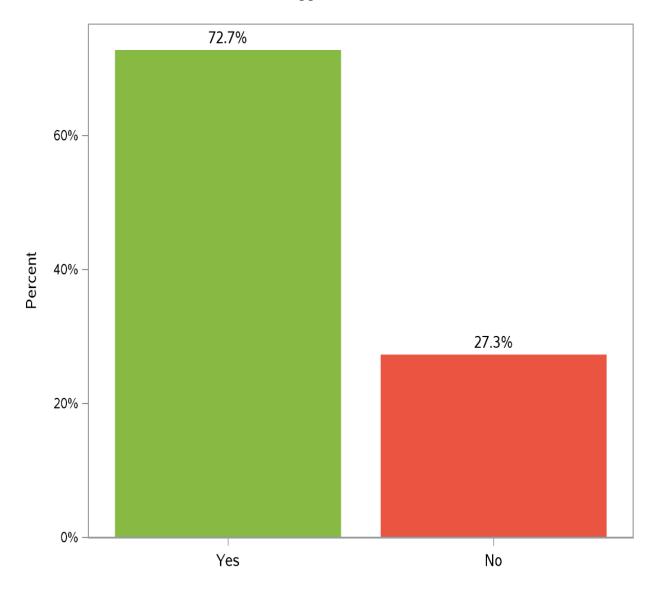
deprescribing.org





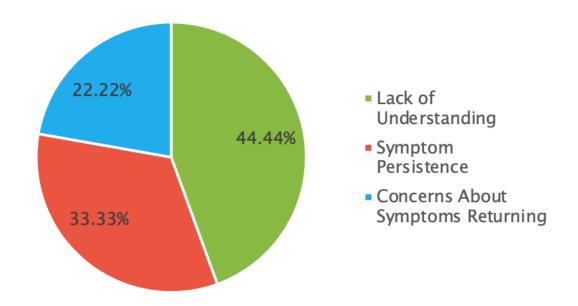


Appendix C



PPI Deprescribed				
			Cumulative	Cumulative
PPIDeprescribed	Frequency	Percent	Frequency	Percent
Yes	24	72.73	24	72.73
No	9	27.27	33	100.00

Appendix D



			Cumulative	Cumulative
Reason	Frequency	Percent	Frequency	Percent
Symptom Persistence	3	33.33	3	33.33
Concerns About Symptoms Returning	2	22.22	5	55.56
Lack of Understanding	4	44.44	9	100.00
Frequency Missing = 24				

Appendix E

Confidence Limits for the Binomial Proportion					
PPIDeprescribed = Yes					
Proportion = 0.7273					
Туре	95% Confidence Limits				
Agresti-Coull	0.5561	0.8510			
Blaker	0.5468	0.8563			
Clopper-Pearson (Exact)	0.5448	0.8670			
Jeffreys	0.5610	0.8556			
Likelihood Ratio	0.5621	0.8584			
Logit	0.5535	0.8516			
Mid-p	0.5581	0.8580			
Wald	0.5753	0.8792			
Wilson	0.5578	0.8493			

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Deprescribing Proton Pump Inhibitors in a Rural Health Clinic

Jason Barney, BSN, RN DNP Project Final Defense April 1, 2024





Acknowledgements

Advisory Team

• Dr. Nicole Harpold, DNP RN AGPCNP-BC

• Dr. Kellie Riley, DNP, FNP-BC



Objectives for Presentation



Investigate the clinical challenge of inappropriate Proton Pump Inhibitor (PPI) use.



Summarize the findings from the organizational assessment



Review the literature supporting deprescribing strategies for PPIs in primary care settings.



Discuss the algorithm and patient education initiated to address inappropriate PPI use.



Disseminate the results and implications of the PPI deprescribing project.



Reflect on the alignment of the project with DNP essentials.



IRB Approval

November 8, 2023

Dear Jason Barney DNP:

If this is a resident project submitted with a faculty member listed as the Principal Investigator, you must submit your project to the Scholarly Activity Review Committee (SARC) for further review by emailing

Although this project does not fall under the oversight of th RB, you still need to follow other institutional policies. If your project involves access to medical records or PHI, you must contact your institutions' compliance / privacy officer. It is also recommended that you consult with any departments that may be impacted by your project to ensure any departmental requirements are met.

Please be advised, it is your responsibility to consult with the IRB, in writing, if any changes are made in the project's current design, procedures, etc. Such changes may necessitate a new complete IRB submission.

If we can be of any further assistance or if you have any questions or concerns, please contact us at or via e-mail at httpp@r

Good luck with your project.

The Office of the IRB does not send a hard copy of documents which have been electronically transmitted. These are the only copies of the regulatory documents you will receive.





Introduction and Background

Deprescribing Guidelines Gap

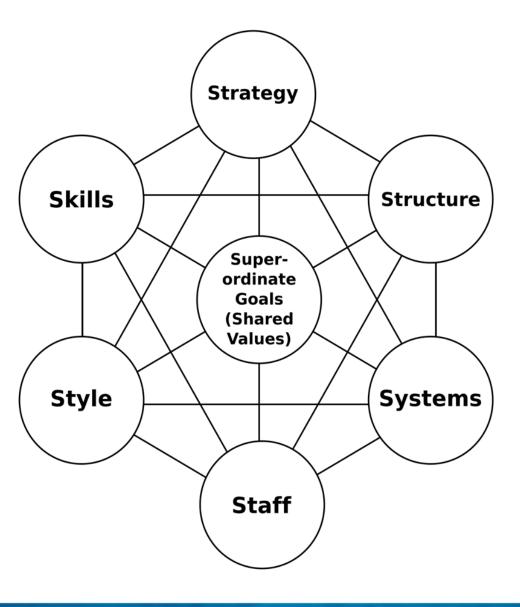
Prevalence of PPI use

PPIs
Inappropriately
Prescribed

Long-Term Risks Challenges
Adhering to
Guidelines



Current State of the Organization: The McKinsey 7S Model



Peters, T. J., & Waterman, R. H. (1982). In search of excellence: Lessons from America's best-run companies.

New York: Harper & Row.



SWOT Analysis S - Strengths

resources to support patient care. within the organization or not filed correctly. The organization is committed to providing Lack of staff knowledge regarding current exceptional care to its patients. clinical-based guidelines for PPI. Lack of dedicated time for staff to engage in a Clear organizational mission, vision, values, and strategic plan with a common goal of quality improvement project.

the project

High rates of noncompliance among the patient enhancing population health and well-being. Deprescribing.org PPI deprescribing algorithm population. and patient education effectiveness. Accessibility and low cost of over-the-counter PPIs at local retailers.

O - Opportunities An increase in knowledge and education will

Buy-in from engaged staff members who are

Large healthcare system with adequate external

committed to improving health outcomes.

- improve patient compliance. Increased adherence of patients will decrease comorbidities and mortality in the patient
- population. Standardized guidelines will Improve adherence to quality measures.

W- Weaknesses

Lack of EMR integration to extract vital data for

Paper-charted documentation can be lost

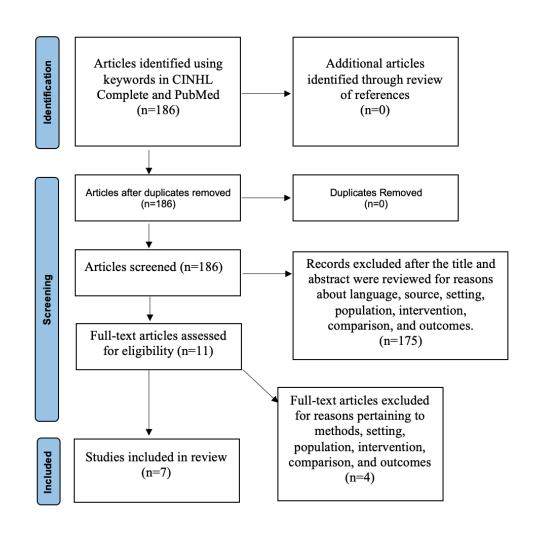
- T Threats
 - Lack of gastroenterologists in the clinical area.
 - Pushback by staff due to changes in their workflow. May view additional work as a burden.
 - Increased time constraints due to high patient volume

Available Knowledge/Evidence

- The purpose of the literature review: Examine existing research to identify successful strategies and approaches for reducing inappropriate and prolonged PPI use in clinical practice.
- The aim of this literature review is twofold: first, to validate the utilization of a deprescribing algorithm for healthcare providers. Second, to explore and identify effective strategies for reducing PPI use among adult patients.



PRISMA Figure





Synthesis of Results

Theme	Literature Synthesis
Barriers for Deprescribing	 Inadequate Healthcare Provider Motivation Lack of Time Patient Resistance Insufficient Provider Resources Unawareness of Inappropriate Medication Use Limited Long-Term Studies
Provider Non-Adherence	 Complex Guidelines Lack of Specific Guidelines for PCPs Increasing Patient Demands and Limited Time Lack of consequences of non-adherence

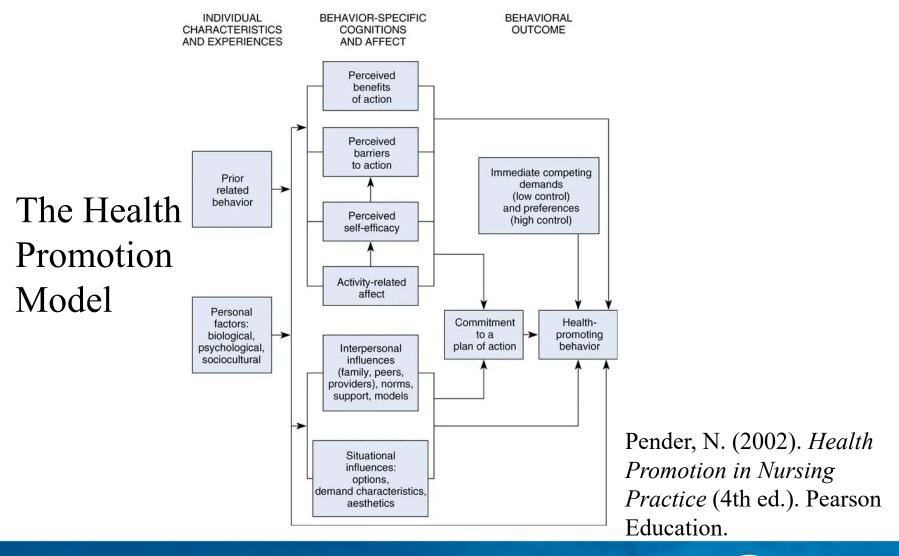


Synthesis of Results

Theme	Literature Synthesis
Facilitators for Deprescribing	 Staying updated with new education and guidelines Conducting medication reviews Providing patient education Engaging in shared decision-making Promoting health
Provider Adherence	 Adherence to a PPI Deprescribing Algorithm Importance of PPI Deprescribing Guideline Role of a PPI Algorithm Patient-Provider Relationship Training and Support

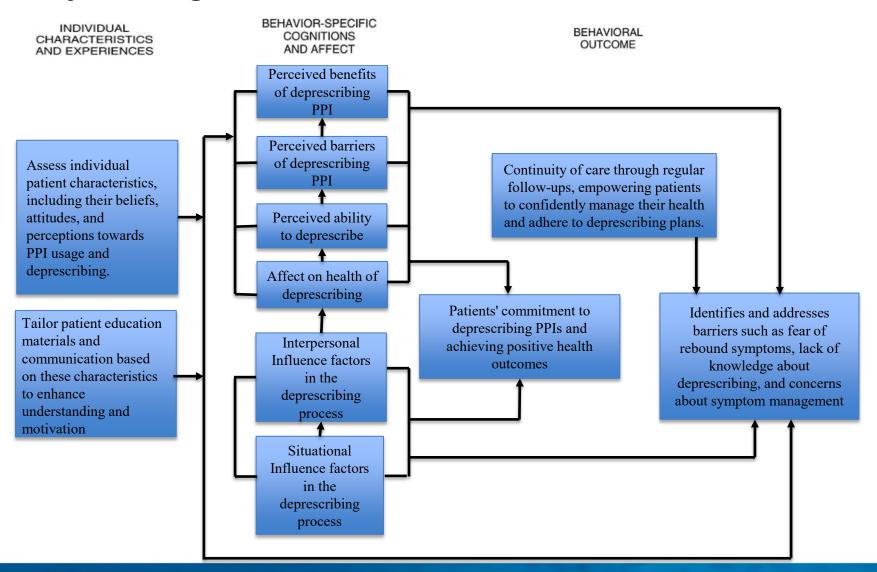


Framework/Conceptual Model for Phenomenon





Project Alignment with Health Promotion Model





Clinical Practice Question

• Does implementing a PPI deprescribing clinical practice guideline and providing patient-centered education reduce the utilization of PPI among eligible patients?



PROJECT PLAN



DNP Project Purpose and Objectives

Project purpose:

The purpose of this project was to address the issue of inappropriate and unnecessary proton pump inhibitor (PPI) use among patients. The goal was to implement a comprehensive deprescribing intervention that combines a provider deprescribing algorithm with patient education to reduce PPI usage where it is no longer medically indicated.

Objectives:

- 1. Quality Improvement in PPI Deprescribing
- 2. Evidence-Based PPI Deprescribing Implementation
- 3. Patient Education and Lifestyle Modification
- 4. Follow-up and Data Collection
- 5. Achieve a 49% PPI Discontinuation Rate (Odenthal et al., 2020)



DNP Project Design and Type

• Quality Improvement Project: Enhancing patient care through a Proton Pump Inhibitors (PPIs) deprescribing algorithm and patient education about reducing usage of PPIs when they are no longer medically indicated.



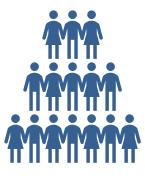
Setting



Large Nonprofit Healthcare System

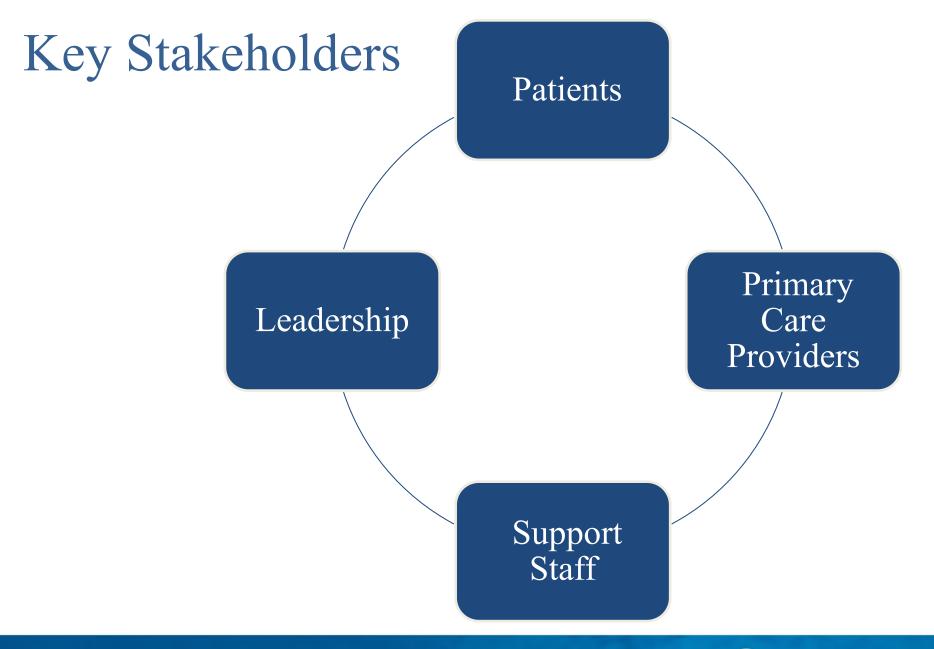


Family Medicine Clinic



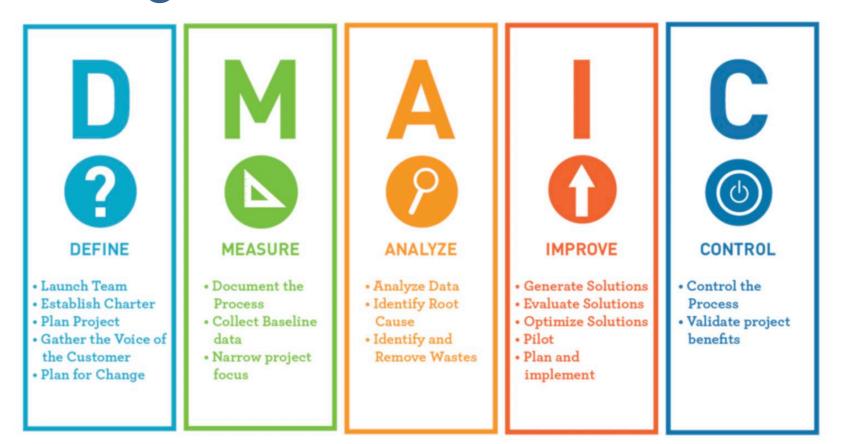
4500 Patients







Implementation Framework: The Lean Six Sigma



Six Sigma Development Solutions. (2021). *DMAIC. what is it? what does it mean?* https://sixsigmadsi.com/dmaic-process/



Implementation Strategies & Elements

Implementation Stuategy	Description	Framework Alignment		
Implementation Strategy	Description	Framework Alignment		
Assess for readiness and identify barriers and facilitators (Powell et al., 2015, p. 8)	 SWOT Analysis Initial conversation with staff to gauge interest / understand patient needs 	DefineMeasure		
Conduct educational meetings (Powell et al., 2015, p. 8)	 Discuss implementation plan with stakeholders to ensure all members have clear understanding of project plan and goal 	DefineImproveControl		
Create a learning collaborative (Powell et al., 2015, p. 8)	 Provide training to educators and communicate throughout the project process 	DefineMeasureImproveControl		



Implementation Strategies & Elements

Implementation Strategy	Description	Framework Alignment
Distribute educational materials (Powell et al., 2015, p. 9)	PPI deprescribing information sheetPPI algorithm	ImproveControl
Purposely reexamine the implementation (Powell et al., 2015, p. 10)	Staff InterviewsConduct phone calls	• Improve
Revise professional roles (Powell et al., 2015, p.9)	Change workflow process	• Improve



Evaluation & Measures

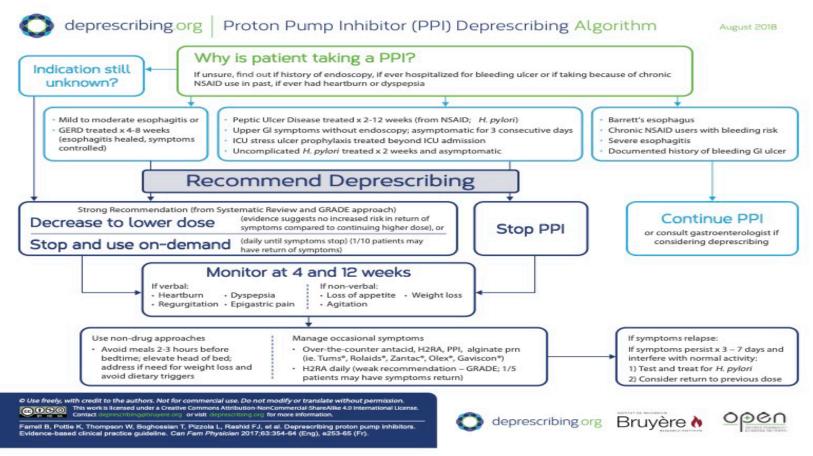
Topic	Concept	How Measured	When Measured	Who Measures
Implementation Strategies	Assess for readiness and identify barriers and facilitators (Powell et al., 2015, p. 8)	 SWOT Analysis Initial conversation with staff to gauge interest / understand patient needs 	Pre-Implementation	Student
	Conduct educational meetings (Powell et al., 2015, p. 8)	Staff interviewsTrack number of staff attended	Pre-Implementation	Student
	Create a learning collaborative (Powell et al., 2015, p. 8)	• Staff interviews	Pre-Implementation	Student
	Distribute educational materials (Powell et al., 2015, p. 9)	Staff interviewsObservation	Pre-Implementation	Student
	Purposely reexamine the implementation (Powell et al., 2015, p. 10)	 Direct observation of workflow Staff interviews 	Post-Implementation	Student
	Revise professional roles (Powell et al., 2015, p.9)	Direct observation of workflowStaff observation	Pre-Implementation	Student



Evaluation & Measures (cont.)

Topic	Concept	How Measured	When Measured	Who Measures
System Outcomes	PCP use of the algorithm and patient education	Staff InterviewObservation	Post implementation	Student
System Outcomes	Provided patient education to eligible patients	 Staff Interview Record of number of educational materials distributed 	Post implementation	Student
System Outcomes	Phone calls were conducted to assess deprescribing outcomes	 Follow-up phone calls Results will be placed on the PPI deprescribing information sheet 	Post implementation	Student





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deprescribing.org | Is a Proton Pump Inhibitor still needed?

August 2018

What are Proton Pump Inhibitors (PPIs)?

Proton Pump Inhibitors, or PPIs, are a class of drugs that are used to treat problems such as heartburn or stomach ulcers.

There are many different types of PPI drugs:

- · Lansoprazole (Prevacid *)
- · Omeprazole (Losec*)
- · Pantoprazole (Tecta*, Pantoloc*)
- · Rabeprazole (Pariet) Esomeprazole (Nexium*)
- Dexlansoprazole (Dexilant*)
- · Omeprazole (Olex*)

Why use less of, or stop using a Proton Pump Inhibitor?

While PPIs are effective at treating many stomach problems, such as heartburn, they are often only needed for a short period of time.

Despite this, many people take PPIs for longer than they may need.

Research shows that for some people, doses can be safely lowered or the drug used just when needed for symptom relief.

PPIs are generally a safe group of medications; however, they can cause headache, nausea, diarrhea and rash. They may also increase risk of:

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Farrell B, Pottle K, Thompson W, Boghossian T, Pizzola L, Rashid FJ, et al. Deprescribing proton pump inhibitors. Evidence-based clinical practice guideline. Can Fam Physiolan 2017;63:354-64 (Engl., e253-65 (Fr).

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- · Low vitamin B12 and magnesium blood levels
- Bone fractures
- Pneumonia
- · Intestinal infections such as C. difficile

Stopping a Proton Pump Inhibitor is not for everyone

Some people need to stay on a PPI for a long time. However, others only need this medication for a short period of time.

When the ongoing reason for using a PPI is unclear, the risk of side effects may outweigh the chance of benefit.

People who should continue on a PPI include those with any of the following:

- · Barrett's esophagus
- · Long-term use of nonsteroidal anti-inflammatory drug (e.g. Advil*)
- · Severe inflammation of the esophagus
- · Documented history of bleeding stomach ulcer

How to safely reduce a Proton Pump Inhibitor

People over the age of 18 who have been taking a PPI for more than 4 to 8 weeks should talk to a doctor, nurse practitioner or pharmacist about whether stopping a PPI is the right choice for them.

Doctors, nurse practitioners or pharmacists can help to decide on the best approach to using less of a PPI. They can advise on how to reduce the dose, whether to stop it altogether, or how to make lifestyle changes that can prevent heartburn symptoms from returning.

Reducing the dose might involve taking the PPI once daily instead of twice daily, lowering the number of mg (e.g. from 30mg to 15mg, or 40mg to 20mg, or 20mg to 10mg depending on the drug), or taking the PPI every second day for some time before stopping.

O deprescribing.org Bruyère



deprescribing.org | Is a Proton Pump Inhibitor still needed?

August 2018

What to monitor after reducing a Proton Pump Inhibitor

After reducing or stopping a PPI with the help of a physician, nurse practitioner or pharmacist, it is important to check for, and report signs of:

- Heartburn
- Reflux
- Stomach pain

If the patient is not able to speak, check for, and report signs of:

- Loss of appetite
- Weight loss
- Agitation

Other ways to reduce heartburn, reflux or stomach pain

Lifestyle changes:

- · Avoid triggers (e.g. coffee, alcohol, spicy foods, chocolate)
- · Avoid food 2-3 hours before bedtime
- · Elevate the head of the bed
- Lose weight

Manage occasional heartburn with over the counter drugs such as:

- Tums'
- · Rolaids
- · Zantac
- · Olex' Gaviscon*

What to do if stomach problems continue

If heartburn, reflux, or stomach pain continues after 3-7 days and interferes with normal activities, please talk to a doctor, nurse practitioner or pharmacist. They can help decide whether to return to a previous PPI dose or whether to use the PPI 'on-demand' (daily until your symptoms stop). They may also suggest a test for a treatable condition called H. pylori.

Personalized	PPI	dose	reduct	ion s	trategy:
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This pamphlet accompanies a deprescribing guideline and algorithm that can be used by doctors, nurse practitioners, or pharmacists to quide deprescribing.



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Farrell B, Pottie K, Thompson W, Boghossian T, Pizzola L, Rashid FJ, et al. Deprescribing proton pump inhibition Evidence-based clinical practice guideline. Can Fam Physician 2017;63:354-64 (Eng), e253-65 (Fr).

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PPI deprescribing information sheet

PPIs:

(E	(France A next to the one the pattern is currently taking)								
Omeprazole (Prilosec)			Pantoprazole (Protonix)						
Esomeprazok (Neximm)			razole (Aciphex)						
Lausoprazole (Prevacid)		Dexlar	Isoprazole (Dexilant)						
Dose:	Duration of Medicatio	l Use	Medical Rationale/Condition for Use:						
Name	Patient Information:								
Date of Birth									
Medical Record Number (MRN):									
Contact Phone Number									
Plan of Care: Please indicate if the patient has discontinued (DC) or tapered their PPI									

Two Week Follow-up

Deprescribed Yes/No	
If no, comments/rationale	



		D	6	5							
7	А	В	С	D	_/	Α	В	C			
1		PPI Deprescribed? Yes	PPI Deprescribed? No	If No, Select Reason (Refer to Key for codes)	1	Code	Description				
2	Sample	X					Computers Descriptors of Debients weight computers or consistent computers				
3	Patient						Symptom Persistence: Patients might experience persistent symptoms				
4	Patient						related to their gastrointestinal condition, such as heartburn or acid reflux,				
5	Patient				_						
6	Patient				2		1 which could lead them to continue PPI use.				
7	Patient						Concerns About Symptoms Returning: Some patients might be concerned				
8	Patient										
9	Patient						that discontinuing the PPI could lead to a recurrence of symptoms, impacting				
10	Patient						2 their quality of life.				
11	Patient				3		z then quality of me.				
12	Patient						Lack of Understanding: Patients may not fully understand the benefits of				
13	Patient				_						
14	Patient						deprescribing or the potential long-term risks of PPI use, leading them to opt				
15	Patient						3 for the status quo.				
16	Patient				4		·				
17	Patient				- 5		4 Other reasons				
18	Patient				_						
19	Patient				6						
20	Patient				7						
21	Patient										
22		1	. 0		8						



Analysis Plan

Measure	Measurement Plan
Agresti-Coull test	Assess whether there is a statistically significant impact of PPI deprescribing on patient outcomes
Deprescribed: Yes	Bar Chart
Deprescribed: No	Bar Chart
Deprescribed: No Frequency coded responses	Pie Chart



Ethical Considerations

Completion of CITI Training

HIPPA compliant.

IRB Determination within a Midwestern Health Care system

De-identified data collection through the removal of direct patient identifiers



Timeline

Activity	2023							20	024	
	Previously Completed	Aug	Sep	Oct	Nov	Dec	Jan	Feb	March	Apr
Identification of project site needs	X									
Project mentor agreement	X									
Prospectus	X									
Organizational Assessment	X									
Literature Review	X									
IRB Application			X	X						
Project Proposal Defense					X					
Pre-Implementation					X					
Implementation						X	X	X		
Post-Implementation									X	
Final Project Defense										X



RESULTS



Inclusion Criteria





Adult Patients aged 18 years and older



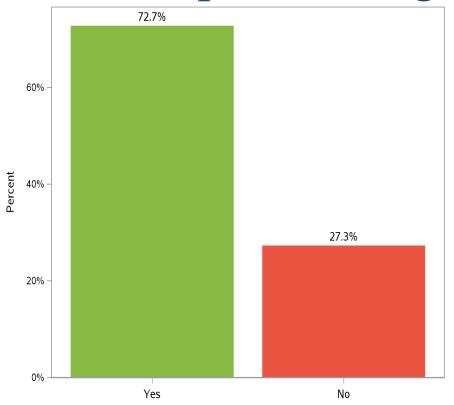
During December 15th, 2023, to February 16th, 2024



Currently using PPIs



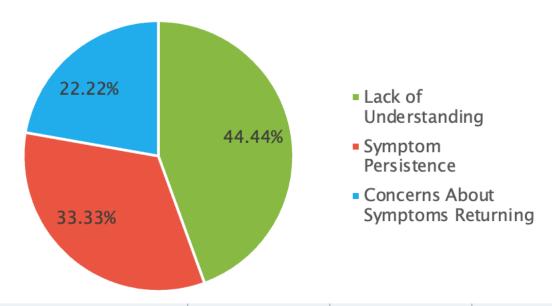
PPI Deprescribing



PPI Deprescribed										
	Cumulative	Cumulative								
PPIDeprescribed	Frequency	Percent	Frequency	Percent						
Yes	24	72.73	24	72.73						
No	9	27.27	33	100.00						



Common Reason for Not Deprescribing



			Cumulative	Cumulative
Reason	Frequency	Percent	Frequency	Percent
Symptom Persistence	3	33.33	3	33.33
Concerns About Symptoms Returning	2	22.22	5	55.56
Lack of Understanding	4	44.44	9	100.00



Statistical Impact

Confidence Limits for the Binomial Proportion PPIDeprescribed = Yes					
Proportion = 0.7273					
Туре	95% Confid	95% Confidence Limits			
Agresti-Coull	0.5561	0.8510			
Blaker	0.5468	0.8563			
Clopper-Pearson (Exact)	0.5448	0.8670			
Jeffreys	0.5610	0.8556			
Likelihood Ratio	0.5621	0.8584			
Logit	0.5535	0.8516			
Mid-p	0.5581	0.8580			
Wald	0.5753	0.8792			
Wilson	0.5578	0.8493			



\$200

\$80

\$1,200

\$20,928

\$12,500

\$2,850

\$1,750

\$800

\$200

\$80

\$0

\$15

\$1,200

\$19,395

\$1,533

37

Budget & Resources		
Revenue		
Billing Code		
CPT Code 99212	\$1,551 (\$47 x 33 patients)	
Project Manager Time (in-kind donation)	\$12,500	
Team Member Time:		
Site Mentor: MD (in-kind donation)	\$2,850	
NP (in-kind donation)	\$1,750	
MA (in-kind donation)	\$800	
Consultations:		

Statistician (in-kind donation)

Student Laptop (in-kind donation)

Site Mentor: MD (in-kind donation)

Project Manager Time (in-kind donation)

Equipment:

Total Income

Team Member Time:

NP (in-kind donation)

MA (in-kind donation)

Statistician (in-kind donation)

Cost of Printing Materials

Student Laptop (in-kind donation)

Consultations:

Equipment:

Cost of Space

Total Expenses

Net Operation Plan

Expenses

MHC Director of Clinical Informatics (in-kind donation)

MHC Director of Clinical Informatics (in-kind donation)

Discussion

- Standardized process for Deprescribing PPIs
 - Easily accessible
 - Increased provider adherence
 - Improved PPI deprescribing
- Implications for practice
 - Patient-Centered Care
 - Long-Term Health Outcomes
 - Increase organizational revenue



Limitations

Small Sample Size

Time Constraints

Staffing Challenges Absence of EHR



Sustainability Plan



LONG-TERM INTEGRATION



CONTINUOUS EDUCATION



TRANSITION TO EHR



DISSEMINATING THE PROJECT OUTCOMES



CHAMPION IDENTIFIED



CONTINUE USE
OF
DEPRESCRIBING
ALGORITHM AND
EDUCATION



HEALTH CARE SCHOLARLY DAY



Conclusion



Primary care clinic



Quality improvement (QI) initiative



Guide the project's implementation



Evaluating the project's impact and effectiveness



Dissemination

GVSU Final Defense Distribution of defense and manuscript to organizational stakeholders Upload into Scholar Works Manuscript submission Health Care Scholarly Day



Handouts

- 1. SWOT Analysis
- 2. Budget & Resources
- 3. PPI Algorithm
- 4. PPI Patient Education
- 5. PPI deprescribing Information Sheet
- 6. Telephone Follow-up Calls Script
- 7. Data management in Excel
- 8. Results
 - A. Bar Chart
 - B. Pie Chart
 - C. Confidence Limits



DNP Essentials Reflection

Essential I	Scientific Underpinnings for Practice	OALiterature Review
Essential II	Organizational and Systems Leadership for Quality Improvement and Systems Thinking	Project leaderStakeholder engagement
Essential III	Clinical Scholarship and Analytical Methods for Evidence-Based Practice	• Utilization of EBP strategies, frameworks, and measures
Essential IV	Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Heath Care	 Analysis of current medical records/quality reporting system Chart audits
Essential V	Health Care Policy for Advocacy in Health Care	 Advocated for screening and reimbursement for deprescribing PPIs of all patients in the organization to improve health outcomes.
Essential VI	Interprofessional Collaboration for Improving Patient and Population Health Outcomes	 Meetings with faculty, clinical staff, and leadership
Essential VII	Clinical Prevention and Population Health for Improving the Nation's Health	 Decreasing comorbidities by increasing provider adherence Disseminate findings to help lead further QI projects
Essential VIII	Advanced Nursing Practice	 Development, implementation, and analyzation of project

(American Association of Colleges of Nursing, 2006)



Acknowledgments and Gratitude

William Bursteinowicz

October 2, 1961 – November 16, 2023

Joshua Bursteinowicz

May 25, 1997 – January 10, 2024







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