

QUALITY IMPROVEMENT

Improving the Appropriate Prescribing of Olanzapine for Chemotherapy-Induced Nausea and Vomiting: A Quality Improvement Initiative for the Outpatient Oncology Practice

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Abstract

Background: Updated American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN) antiemetic guidelines recommend olanzapine for the prophylactic treatment of chemotherapy-induced nausea and vomiting (CINV) in highly emetogenic chemotherapy (HEC). Inadequate treatment of CINV can result in compounding physical sequelae, ultimately affecting patients' tolerance and recovery throughout chemotherapy treatment. Regional Michigan Oncology Quality Consortium (MOQC) data have identified a wide range of compliance rates in the appropriate prescribing of olanzapine. Literature has shown that olanzapine is safe and effective for the treatment of acute and delayed CINV. **Purpose:** The purpose of this quality improvement (QI) project was to improve the compliance rate of appropriate prescribing of olanzapine for CINV for adult patients receiving HEC within the project site's outpatient oncology clinic. **Methods/Procedures:** The project was based on the Plan-Do-Study-Act (PDSA) model and implemented in an outpatient oncology clinic in a Midwestern urban area over a 6-month time period. A multidisciplinary and interactive education program was delivered to providers. Pre- and post-intervention data were collected by impartial, independent auditors. At monthly provider staff meetings, a presentation was provided to prescribers supplying information on the updated antiemetic guideline recommendations and the pharmacodynamics of olanzapine. An olanzapine frequently asked questions (FAQ) sheet was also

provided to reinforce the reviewed material. **Results:** Data collected following implementation showed an increase in appropriate prescribing of olanzapine from 82.05% to 94.74% ($n = 76$). A standard deviation Z-test for two population proportions showed the positive change in compliance rate was statistically significant at $p < .05$ where p was calculated at .02852. A sustainability audit 1 year after completion showed the rate of appropriate prescribing of olanzapine at 92.59% ($n = 27$), representing a decrease of 2.15 percentage points. A standard deviation Z-test demonstrated the decrease in comparative compliance rates was not statistically significant at $p < .05$.

Conclusion/Interpretations: Audit data obtained following the implementation of the QI project revealed a statistically significant improvement, which supported the hypothesis that providing education based on the PDSA model is an effective method to improve the compliance rate of appropriate olanzapine prescribing for CINV in patients receiving HEC. The result reflects the growing body of evidence confirming the validity of the PDSA model.

Chemotherapy-induced nausea and vomiting (CINV) is one of the most prevalent side effects associated with systemic cancer treatments, and often the most distressing. It affects up to 80% of patients (Gupta et al., 2021). Guidelines to address CINV have been established in the United States by the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN).

Chemotherapy agents are divided into four categories based on the potential emetogenic effect, also described as emetic risk, that the agent may exhibit. Razvi and colleagues (2019) describe these categories as high risk ($> 90\%$ frequency of CINV), moderate risk (30%–90% frequency of CINV), low risk (10%–30% frequency of CINV), and minimal risk ($< 10\%$ frequency of CINV). The ASCO and NCCN guidelines were updated in 2017 and 2018, respectively, which included new recommendations to include olanzapine (Zyprexa) for patients receiving chemotherapy categorized as highly emetogenic chemotherapy (HEC; Razvi et al., 2019). These recommendations were based, in part, on research by Navari and colleagues (2016) that showed olanzapine, when compared with placebo, significantly improved CINV in patients who were receiving HEC. However, even with guidelines supported by evidence-based research, there has been hesitancy in some health-care providers to prescribe olanzapine for CINV (MacKintosh, 2016).

Olanzapine is an atypical antipsychotic that was initially introduced in 1991 and approved in 1996 to treat schizophrenia, bipolar I depression,

and treatment-resistant major depressive disorder. However, olanzapine can also help treat nausea and vomiting, particularly in cases induced by chemotherapy. It exerts this effect through its antagonistic action on various receptors, including serotonin, dopamine, muscarinic acetylcholine, and histamine (H1) receptors (Osman et al., 2018).

The purpose of this quality improvement (QI) initiative was to design and implement an evidence-based intervention to improve the percentage rate at which olanzapine is appropriately prescribed for CINV in patients receiving HEC in outpatient oncology clinics. Advanced practice providers (APPs), as well as oncology fellows and attending physicians, are often tasked with addressing CINV that patients experience while receiving treatment. It is therefore important that all members of the patient's care team be educated on the most current and up-to-date antiemetic guidelines. Given the addition of olanzapine is a new indication for prevention of CINV, it is necessary to establish practice procedures and education that facilitate the dissemination of revisions or updates in previously delineated treatment recommendations.

CONTEXT/BACKGROUND

It is essential that CINV be adequately addressed. Uncontrolled CINV can quickly lead to multiple compounding sequelae conditions such as electrolyte imbalances, dehydration, physical damage from erosion to the esophagus, and harm to the diaphragm muscles due to strain. If nausea worsens, diet and hydration, which are essential for patients with cancer undergoing chemotherapy, could be affected (Gupta et al., 2021). Additionally, a study

by Craver and colleagues (2011) showed the direct costs associated with CINV events in the US totaled 26 million for outpatient participants.

The Michigan Oncology Quality Consortium (MOQC) is a voluntary collaboration of medical and gynecology oncology practices that work together with the goal of improving the quality of cancer care in the Great Lakes Michigan region. While MOQC is physician-led, it also works with all health-care professionals, patients, and family caregivers to identify specific areas of need to enhance care or improve quality. A measures committee at MOQC meets annually to identify gaps in care and variation in care, and use evidence-based guidelines in the selection of new measures or quality initiative priorities. In 2020, MOQC introduced the CINV – Antiemetics Initiative. This initiative aims to increase the appropriate prophylactic prescribing of olanzapine for HEC, with a target compliance rate of 100% (MOQC, 2023). As part of the initiative, medical oncology practices participating in MOQC conducted a self-audit looking at the compliance rate (represented by a percentage) in which each clinic appropriately prescribed olanzapine for HEC. The MOQC audit noted compliance rates in 2021 for the participating outpatient oncology practices ranged from 1% to 93%, which suggests that there has been a varied degree of understanding of the revised ASCO and NCCN antiemetic guidelines pertaining to olanzapine (Griggs, 2022). While all practicing providers (doctors of medicine [MDs], doctors of osteopathic medicine [DOs], nurse practitioners [NPs], and physician assistants [PAs]) can prescribe antiemetics, it is often the role of APPs to conduct chemotherapy teaching classes prior to the initiation of therapy, at which time antiemetics are usually prescribed. MOQC and its participating outpatient oncology practices have therefore been looking for an effective intervention that could be implemented in each clinic that would increase the compliance rate of appropriate olanzapine prescribing.

PURPOSE OF STUDY

The goal of this Doctor of Nursing Practice (DNP)-led QI initiative was to improve the appropriate prescribing of olanzapine for CINV in patients receiving HEC. By the end of the QI project's

6-month assessment period, prescribing providers (MDs, DOs, NPs, and PAs) at the targeted outpatient clinic would improve the overall percentage of appropriate prescribing of olanzapine for CINV to > 85% of applicable cancer patients receiving chemotherapy categorized as high emetic potential. After completion of the 6-month assessment period, the project coordinator and clinic medical director would discuss plans to implement a permanent, sustainable change in the standard of education and rate of implementation of this protocol. In addition, there would be a discussion on how these outcomes could pertain to disseminating new evidence-based practices such as the ASCO and NCCN CINV guidelines in the future.

METHODS

When selecting the interventional strategy for the QI project, it was determined that a model capable of facilitating at least one, but preferably multiple, cycles of improvement would be needed. The Plan-Do-Study-Act (PDSA) model was ultimately selected as it allows for continuous data collection and small-scale testing (Knudsen et al., 2019). The following sections provide a detailed breakdown of the PDSA cycle for this QI project (Figure 1).

According to Abuzied and colleagues (2023), the PDSA model is a “systematic process improvement strategy consisting of cycles of improvement processes” (p. 70). The primary goal of each PDSA cycle is to provide a structured process of improvement consistent with the scientific method for experimentation. Abuzied and colleagues (2023) explains that “consecutive iterations of the cycle constitute a framework for continuous learning through testing of changes” (p. 71). Each PDSA cycle involves planning, implementing, analyzing results, and taking action based on the findings (Abuzied et al., 2023).

Plan

The intent was to test whether providing education to prescribing providers would produce a statistically significant increase in the percentage of patients that are appropriately prescribed olanzapine. The test compared the percentage of patient encounters, pre- and post-implementation, where olanzapine was appropriately prescribed for HEC by each prescribing provider in the

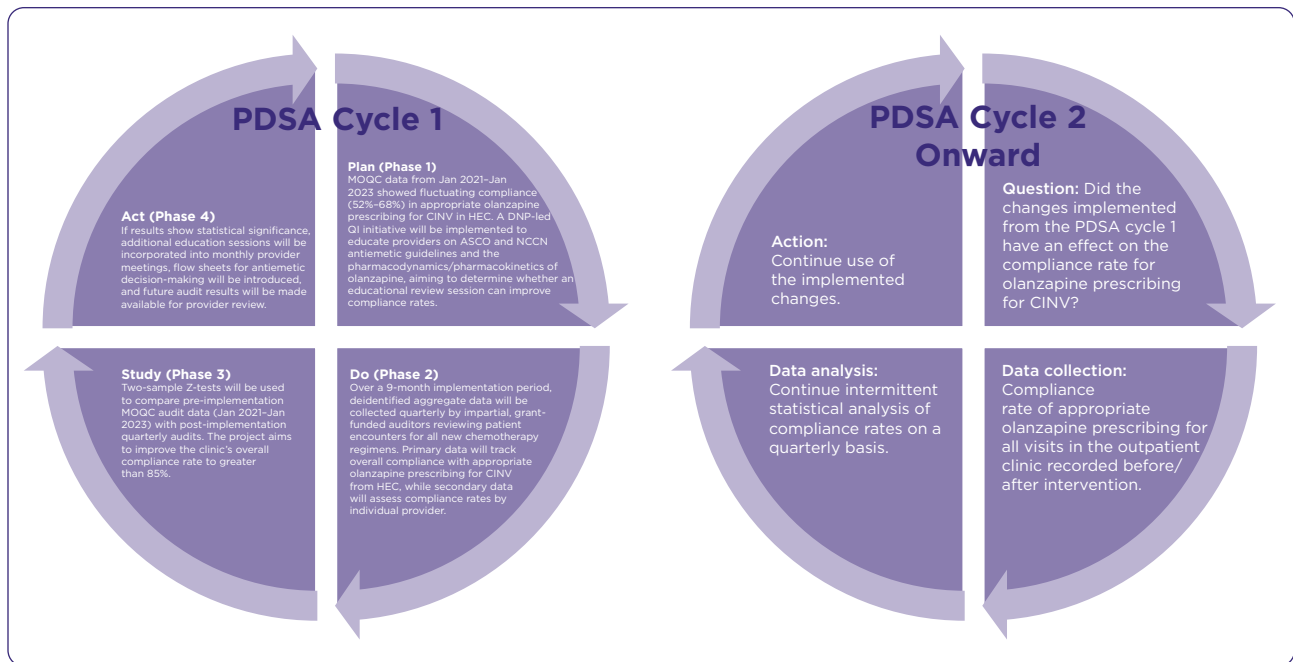


Figure 1. PDSA Cycles 1 and 2. PDSA = Plan-Do-Study-Act; MOQC = Michigan Oncology Quality Consortium; CINV = chemotherapy-induced nausea and vomiting; HEC = highly emetogenic chemotherapy; DNP = Doctor of Nursing Practice; ASCO = American Society of Clinical Oncology; NCCN = National Comprehensive Cancer Network.

outpatient project site clinic. MOQC data from January 2021 showed the target outpatient clinic site compliance percentage was 52%. This data was the basis for the creation of the QI project. A follow-up audit from September 2022 through February 2023 demonstrated a compliance rate of 82%. This data was used as the pre-intervention baseline. The QI project was conducted over a 6-month time period. Testing was conducted at the Karmanos Cancer Institute at McLaren Greater Lansing outpatient hematology and oncology clinic. The goal of the project was that > 85% of applicable patients would have been appropriately prescribed olanzapine, which would be an increase of at least 33% compared to baseline audit data.

Data were collected by an impartial, independent audit team authorized by the project site medical director and regional director of operations and trained to correctly audit, record, and organize pertinent data for later review. Audits were conducted on a biannual basis (every 6 months) and available for preliminary evaluation approximately 2 weeks after each audit period ended.

Prior to implementation of the QI project, approval to proceed was obtained from the Institutional Review Board (IRB) at Michigan State University. Once the final QI project proposal had been reviewed and approved by a faculty advisor, the official IRB Determination Form was submitted. Given this project was categorized as non-human participant research, it was anticipated that the project would be deemed exempt from full institutional review. All data obtained during the audit process were deidentified and securely stored on a computer system requiring two-factor authentication. The computer mainframe was kept locked at the project site clinic office requiring a physical key lock and electronic badge authorization for access. The deidentified data were collected during the audit process by qualified, impartial staff members and only aggregate data required for quantitative statistical analysis were disclosed with the research team. Audits were initially conducted every 3 months. However, during the implementation and testing phase of the QI project, MOQC policy committee members decided that the independent audits would be changed from

every 3 months to biannual and include a 6-month audit period. The change was made to help lower the cost associated with reimbursing the auditors' hourly pay rate. Additionally, the change was instituted to make the audit process easier for each participating clinic group since the audit process is quite time consuming.

Do

A comparison was made between data collected pre- and post-intervention implementation of the percentage rate at which olanzapine was appropriately prescribed. An educational review session was held for prescribing providers at the project site's monthly provider/staff meeting, which included an updated analysis of the ASCO and NCCN guidelines pertaining to antiemetic recommendations, a pharmacist-led review of the pharmacodynamics and pharmacokinetics of olanzapine for an antinausea indication, and a question-and-answer follow-up session for further clarification and to dispel preconceived, inaccurate beliefs or misconceptions.

Given olanzapine has preexisting FDA indications to treat schizophrenia and bipolar I disorder, patients have expressed concerns that they would be labeled as having a mental health disorder if they were to be seen taking olanzapine. Therefore, it is important to provide an in-depth review of why olanzapine is being given, specifically to prevent CINV, and to reassure patients that taking olanzapine in no way indicates a new diagnosis of concurrent mental health disorders.

As a result of the education review session, it was anticipated that prescribing providers would have a better understanding of olanzapine and the updated ASCO/NCCN antiemetic guidelines leading to increased cognizance and willingness to prescribe olanzapine. Providers were encouraged to approach the DNP QI project team lead with any questions about the information in the education session or the QI project itself.

Study

The pre- and post-implementation data were reviewed on a quarterly basis, with the first anticipated data review in June 2023 and a follow-up/final data collection cycle in September 2023 prior to the planned completion of the DNP-led project. If the quarterly data collection did not preliminar-

ily indicate an upward trend in compliance percentage, further adjustments in the PDSA cycle would have been initiated or additional educational remediation would have been provided at subsequent monthly staff/provider meetings.

Act

Future PDSA cycles were planned based on any updates to the ASCO/NCCN antiemetic guidelines as it pertained to olanzapine in the setting of this QI project. If there were any unforeseen barriers in any phase of the PDSA cycle, the issue in question would be assessed and adjustments would be made as indicated. The project site medical director would be consulted to remedy any institutional difficulties such as providers missing the mandatory meeting. With the assumption that there were no barriers, the medical director would be updated on the preliminary findings at each phase of the study. Regular meetings were held with the audit team to ensure accurate data and recorded based on the recommendations of the biostatistician for each quarterly session. If the QI intervention was found to produce a statistically significant increase, an easy-to-follow flow sheet would be introduced summarizing the findings and recommendations for future reference.

RESULTS

The QI initiative test phase concluded in August 2023. Independent auditors reviewed all patient encounters from March 2023 through August 2023 and identified applicable cases pertaining to patients starting systemic chemotherapy categorized by high emetogenic potential. During the 6-month testing period, auditors found 76 such cases. For each of the 76 cases, auditors were tasked with determining if olanzapine was appropriately prescribed, with the parameters that the designated prescribing provider needed to have olanzapine prescribed to the patient's pharmacy prior to the initiation of cycle 1 of chemotherapy. Cases where patients received chemotherapy as inpatient status were excluded since antiemetics were not always prescribed and administered by health-care providers contracted with the target outpatient clinic site.

After a thorough review of each applicable case, auditors found that patients were appropriately

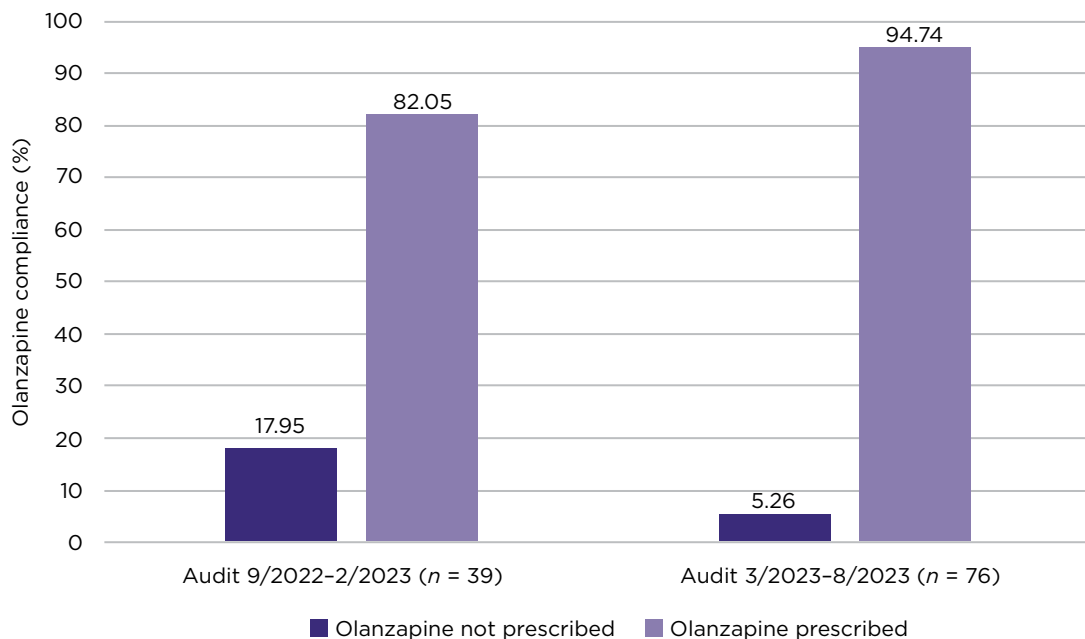


Figure 2. Comparison of appropriate olanzapine prescribing rates pre- and post-intervention.

prescribed olanzapine in 72 of the 76 cases, which equates to a 94.74% compliance rate. This was an increase of 42.7 percentage points (up from 52%) from the initial compliance rate in 2021 and an increase of 12.7 percentage points compared to the baseline audit in September 2022 (up from 82.05%; Figure 2). The audit also showed the compliance rate of each individual prescribing provider. It was noted that one provider was responsible for three of the four cases where olanzapine was not appropriately prescribed. Data are shown in Tables 1 through 3.

Statistical analysis options were discussed with a biostatistician, at which time it was recommended that a standard deviation Z-test for two population proportions would be used to determine statistical significance. A two-sample Z-test is used when trying to determine whether two populations, or groups, differ significantly on a single characteristic (Bobbitt, 2022). The value of z was 2.1897. The value of p was .02852. The result was therefore statistically significant at $p < .05$.

As part of the sustainability process, a quarterly audit was conducted 1 year post-implementation to determine the long-term effectiveness

of the QI project strategies. Auditors found that of the applicable cases between September 2024 and December 2024, patients were appropriately prescribed olanzapine in 25 out of 27 cases, which equates to a 92.59% compliance rate and is represented in Table 2. Comparing the post-implementation audit results to the 1-year sustainability audit results, appropriate olanzapine prescribing compliance rates only decreased by 2.15 percentage points (Figure 3).

Repeat statistical analysis again utilized a two-sample Z-test to determine if the decrease in compliance rate was statistically significant. The value of z was -0.4086 . The value of p was .6818. The result was therefore not statistically significant at $p < .05$.

CONCLUSION

Audit data obtained following the implementation of the QI project revealed a statistically significant improvement, which supported the hypothesis that providing education based on the PDSA model is an effective method to improve the compliance rate of appropriate olanzapine prescribing for CINV in patients receiving HEC. The result

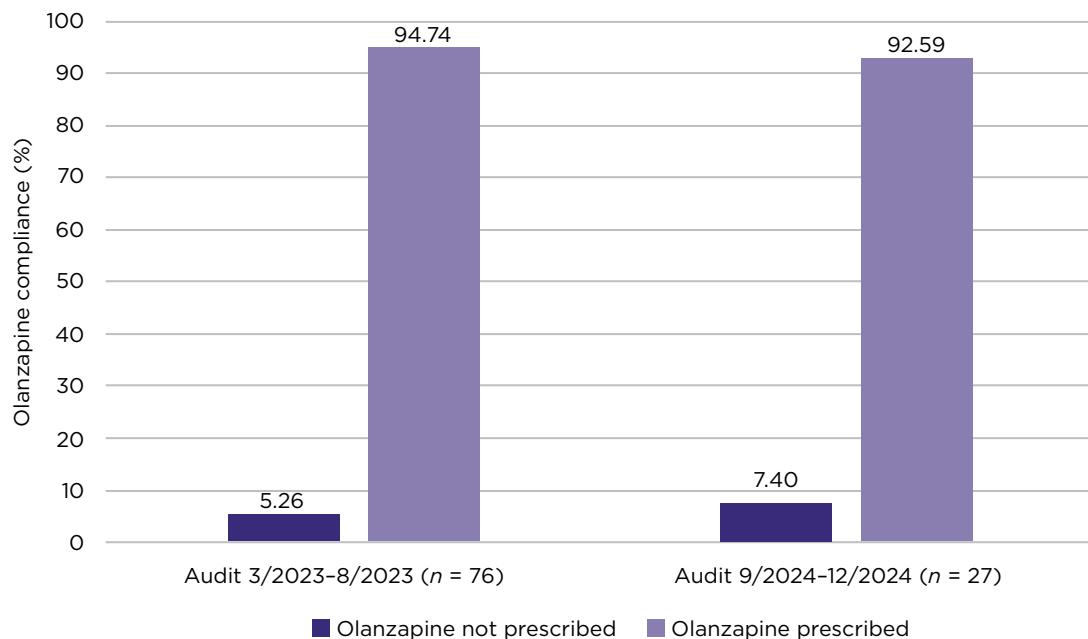


Figure 3. 1-year sustainability audit of appropriate olanzapine prescribing rates.

reflects the growing body of evidence confirming the validity of the PDSA model.

The initial audit data in 2021 showed a considerably lower compliance rate of 52%. The increased compliance rate compared to the pre-intervention baseline in 2022 could not be established. However, discussion with the target outpatient clinic site's medical director indicated that the updated ASCO and NCCN antiemetic guidelines were still relatively new. The increase in compliance rate could be due to independent provider initiatives in understanding and self-implementation of the olanzapine recommendations. While there was a marked improvement pre-intervention, the gap between 100% compliance was likely a result of incomplete understanding of the guidelines across the clinic.

The 1-year post-implementation sustainability audit further demonstrated the effectiveness of the QI project's implementation strategies. While there was a 2.15 percentage point decrease in the compliance rate, it was determined that the difference was not statistically significant.

Ensuring a continued upward trend becomes more difficult as compliance rates approach 100%, as there will inevitably be human errors not attributed to understanding the antiemetic guidelines. These would include computer interface issues or simply forgetting to send the prescription during the patient-provider chemotherapy education class.

Individual provider compliance prescribing rates showed that one of the providers was responsible for three of the four missed cases. A

Table 1. Compliance Rates of Each Prescribing Provider After Intervention

Provider	No. of applicable cases/encounters	Olanzapine prescribed	Olanzapine NOT prescribed
Provider 1	4	4	0
Provider 2	14	11	3
Provider 3	17	17	0
Provider 4	41	40	1

Table 2. Compliance Rates of Each Prescribing Provider 1 Year After Intervention

Provider	No. of applicable cases/encounters	Olanzapine prescribed	Olanzapine NOT prescribed
Provider 1	5	4	1
Provider 2	8	8	0
Provider 3	6	6	0
Provider 4	8	7	1

reeducation session revealed that the provider was using their own chemotherapy class education material that did not accurately reflect all of the chemotherapy regimens categorized as highly emetogenic. During the education meeting, the provider was encouraged to use ASCO and NCCN guidelines or MOQC-approved material to ensure all patients receiving HEC would receive olanzapine.

The scope of the QI project was limited to only determining the appropriate prescribing of olanzapine by providers. The scope initially considered including ways to determine if similar education for patients would positively affect compliance with taking olanzapine, but it was determined that a separate QI project would be needed to fully investigate this aspect. The study's methods also identified a difference in sample size between pre- and post-intervention audits. This was mainly due to the change enacted by MOQC from a 3-month audit period to 6-month audit period. However, this difference in sample size was taken into account and still accurately reflected significance with appropriate statistical analysis using two-population Z-tests.

Implications derived from this study that merit further exploration also include consideration for the discontinuation of olanzapine after chemotherapy treatment has been completed. Discussion with primary care providers has highlighted how often patients wish to continue taking the olanzapine due to its known sedative effect as well as its potential for mood stabilization. This study

did not address this aspect of medication management, and there is a potential for further research or cross-collaboration discussion between the oncology specialty and primary care.

The results from this QI project helped to validate the PDSA model as an effective implementation strategy for other outpatient oncology clinics seeking to affect change in their providers' compliance rates pertaining to appropriate olanzapine prescribing as an antiemetic. By using the PDSA model, any unforeseen barriers after the implementation stage commences can be assessed and adjustments made to subsequent cycles. In this manner, the working model was malleable. This allowed for changes in education if needed but still guided the testing of the hypothesis in a standardized fashion that could ultimately account for said variables once in the data analysis phase of the study.

INTERPRETATION

Cancer treatments are often associated with side effects that can vary depending on the chemotherapy regimen and length of course. One of the most prevalent side effects associated with systemic cancer treatments, and often the most distressing, is CINV. The ASCO and NCCN antiemetic guidelines, updated in 2016 and 2017, respectively, recommend that patients receiving HEC be prescribed olanzapine to be used prophylactically (Razvi et al., 2019).

Regional data from MOQC self-audits in 2021 showed an average of a 23% compliance rate in the appropriate prescribing of olanzapine for CINV in patients receiving HEC. Despite nationally recognized antiemetic guidelines published by ASCO and NCCN, olanzapine prescribing rates have continued to lag in the Great Lakes region and nationally (Griggs, 2022). This demonstrates that there is a need for outpatient oncology clinics to address antiemetic prescribing practices,

Table 3. Total Cases Olanzapine Appropriately Prescribed

Audits	Cases
09/2022-02/2023	32/39 (82.05%)
03/2023-08/2023	72/76 (94.74%)
09/2024-12/2024	25/27 (92.59%)

specifically looking at how and when prophylactic olanzapine is ordered.

Multidisciplinary, interactive evidence-based education based on the PDSA model has been shown to be an effective implementation strategy in many QI studies (Cornell & Powers, 2022; Fox et al., 2023; Gyekye-Mensah et al., 2022; Rollinson et al., 2021; Seton et al., 2022; Sugarman et al., 2021; Vallabhaneni et al., 2022). It was therefore decided that this QI project would include a team-based approach in providing a comprehensive educational review of olanzapine and its use in CINV in patients receiving HEC. Members from pharmacy, infusion nurses, and social work as well as the prescribing providers were included in all phases of the study in an effort to obtain different views. The educational review sessions were presented at monthly provider staff meetings and with one-on-one sessions as needed with printed material provided to reinforce the major learning points. The goal of this QI project was to improve the compliance rate of olanzapine prescribing at the project clinic site by providing education based on a multidisciplinary approach.

After implementation of the QI project, the MOQC audits showed that education in the form of informative handouts, Q&A discussion sessions, and one-on-one teaching opportunities improved compliance to 94.74%. This was an increase of 42.7 percentage points compared to the initial audit in 2021, and an increase of 12.7 percentage points compared to the baseline audit in September 2022. It is likely that continued reminders and education sessions will be needed to ensure compliance rates of olanzapine remain as close to 100% as possible.

The long-term, positive outcomes of effective control of CINV in patients receiving HEC can be established with the creation of provider education programs based on the PDSA model aimed at disseminating and emphasizing the importance of the appropriate prescribing of olanzapine. Addressing CINV in patients receiving HEC is an important aspect of oncology practices that can easily be implemented in any outpatient office. Staff meetings and one-on-one education sessions are an easy way to connect with prescribing providers in outpatient clinics and can help them to understand the value of controlling nausea caused by chemotherapy. ●

Disclosure

The authors have no conflicts of interest to disclose.

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