

QUALITY IMPROVEMENT

Effects of a Revision to the Standard Admission Order Set on Laxative Prescribing for Opioid-Induced Constipation

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Authors' disclosures of conflicts of interest are found at the end of this article.

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Abstract

Purpose: Opioid-induced constipation (OIC) is highly prevalent in patients with cancer-related pain on opioid analgesics and has negative consequences on physical and psychological well-being and quality of life. Oncology clinical practice guidelines recommend the use of osmotic and stimulant laxatives for the prevention and management of opioid-induced constipation, not stool softeners such as docusate sodium. Prescribing practices continue to fall behind these recommendations. **Methods:** This quality improvement project revised the laxative options available in the standard admission order set in the electronic medical record. Specifically, docusate sodium was removed and replaced with senna and polyethylene glycol 3350. **Results:** A total of 2,742 patient admissions preintervention were compared to 2,752 admissions postintervention. The number of orders for docusate ($p < .001$) and docusate-senna ($p = .002$) orders decreased significantly after the intervention, in addition to the number of OIC diagnoses ($p < .001$). However, the number of orders for polyethylene glycol ($p = .559$), senna ($p = .582$), other laxatives ($p = .245$), or functional bowel disorder medications ($p = .533$) did not change significantly. No significant differences were observed in the frequency of laxative orders placed within 24 hours of an opioid order, number of laxatives prescribed at discharge, admissions related to bowel-related complications, or length of stay. **Conclusions:** Interventions utilizing the electronic medical record can facilitate evidence-based management of OIC. Development of clinical practice guidelines and tailoring these interventions further is needed to adapt this approach at other institutions and sustain practice change.

Patients with cancer commonly experience pain requiring the use of opioid analgesics (World Health Organization, 2020). While opioids can provide significant relief of cancer pain, they are associated with a wide range of adverse effects, including nausea, vomiting, constipation, drowsiness, and dry mouth (Corli et al., 2019). Unlike other opioid-related side effects, opioid-induced constipation (OIC) occurs irrespective of opioid dose or drug type and persists without tolerance (Roeland et al., 2020; Sayuk et al., 2023). Not only is OIC highly prevalent, occurring in 44% to 86% of patients with cancer receiving an opioid, but it is also associated with physical complications, including fecal impaction, obstruction, and/or worsening pain (ALMouaalamy, 2021; Sayuk et al., 2023). Opioid-induced constipation is also associated with negative impacts on health-related quality of life and increased health-care costs (Argoff, 2020; Kaye et al., 2023).

The general approach to the prevention and management of OIC includes the use of non-pharmacologic interventions, addressing underlying causes when possible, and laxative therapy (Farmer et al., 2019). Management of OIC may require laxatives from different classes and escalation in doses before deemed “laxative-refractory” (Crockett et al., 2019). The most commonly used laxative drug classes include stimulants (senna, bisacodyl), osmotics (lactulose, milk of magnesia, polyethylene glycol), bulking agents (psyllium), and softeners (docusate; Lexicomp, 2023). Both stimulants and osmotics are preferred because they are well tolerated and equally beneficial in cancer patients (Ginex et al., 2020). When constipation is refractory to traditional laxatives, use of newer agents such as peripherally acting μ -opioid receptor antagonists (PAMORAs) are recommended (Jesuyajolu et al., 2023). Stool softeners and bulking agents are not recommended for the prevention or management of OIC (Larkin et al., 2018; NCCN, 2023a; NCCN, 2023b). Studies have shown docusate with senna is no more effective than senna alone in treating OIC and does not decrease the risk of bowel cramping in hospitalized cancer patients (Hawley & Byeon, 2008; Tarumi et al., 2013). A retrospective observational study of hospitalized patients found those who received at least one dose of docusate were significantly older, had a longer length of stay, had

more medical problems, and were less likely to be discharged to home (MacMillan et al., 2016). For patients who have undergone surgery, a randomized control trial showed docusate was no more effective than placebo in reducing the prevalence of constipation (Weekes et al., 2021). In addition, a randomized control trial using an osmotic or stimulant laxative found a significant reduction in the severity of constipation (Al-Naeem et al., 2018). More recently, monotherapy with docusate has been found ineffective for the prevention of constipation in patients receiving opioids following elective orthopedic surgery (Yang et al., 2022).

The role of stool softeners has been debated in the literature, particularly among palliative care specialists who care for seriously ill patients on opioids for chronic pain. Pain and palliative care experts recommend against docusate when prescribing laxatives for patients on opioid therapy with or without cancer (Saha et al., 2020). The Canadian Society of Palliative Care Physicians (2020) lists the use of stool softeners alone as one of five interventions providers and patients should avoid. In addition to the lack of clinical benefit of docusate for OIC, its administration requires a considerable number of nursing hours and is associated with high costs (Kaye et al., 2023). This has prompted some physicians to call for the removal of docusate from hospital pharmacy formulary stock (Fakheri & Volpicelli, 2019).

To prevent the burden of OIC, current clinical practice guidelines strongly recommend the use of laxatives for prevention and as first-line medical management (Engle & Winans, 2021). More recently, guidelines are omitting the use of stool softeners such as docusate and instead recommend use of a stimulant with or without an osmotic laxative (NCCN, 2023a; NCCN, 2023b). Despite these recommendations, prophylactic and therapeutic laxatives are not consistently prescribed to patients with cancer on opioids (Brown et al., 2020; de Bruin et al., 2019). Additionally, docusate continues to be prescribed in the hospital and community setting, while other laxatives are not used, contributing to suboptimal management of OIC (MacMillan et al., 2016; Brown et al., 2020; Kaye et al., 2023). In this article, there is a description of the findings of a quality improvement project in which the standard admission order set in the electronic medical

record (EMR) was edited to replace docusate sodium with polyethylene glycol 3350. The aim for this project was to improve the prescribing practices of physicians and advanced practice providers (APPs) for the prevention and management of OIC in hospitalized adults with cancer.

METHODS

This quality improvement project used the Knowledge to Action (KTA) model as the guiding framework (Graham et al., 2006). The KTA model is an integration of key knowledge translation

concepts including knowledge creation and research utilization. Figure 1 illustrates this model's knowledge creation process as a funnel and application of the knowledge (action cycle) as a cycle of arrows. This project took place in an acute care National Cancer Institute–designated tertiary cancer center in New York City. At this site, primary oncology teams are responsible for ordering a bowel regimen for patients. The primary teams consist of physicians and/or APPs who enter the admission orders and perform daily management. The registered nurse documents the number and

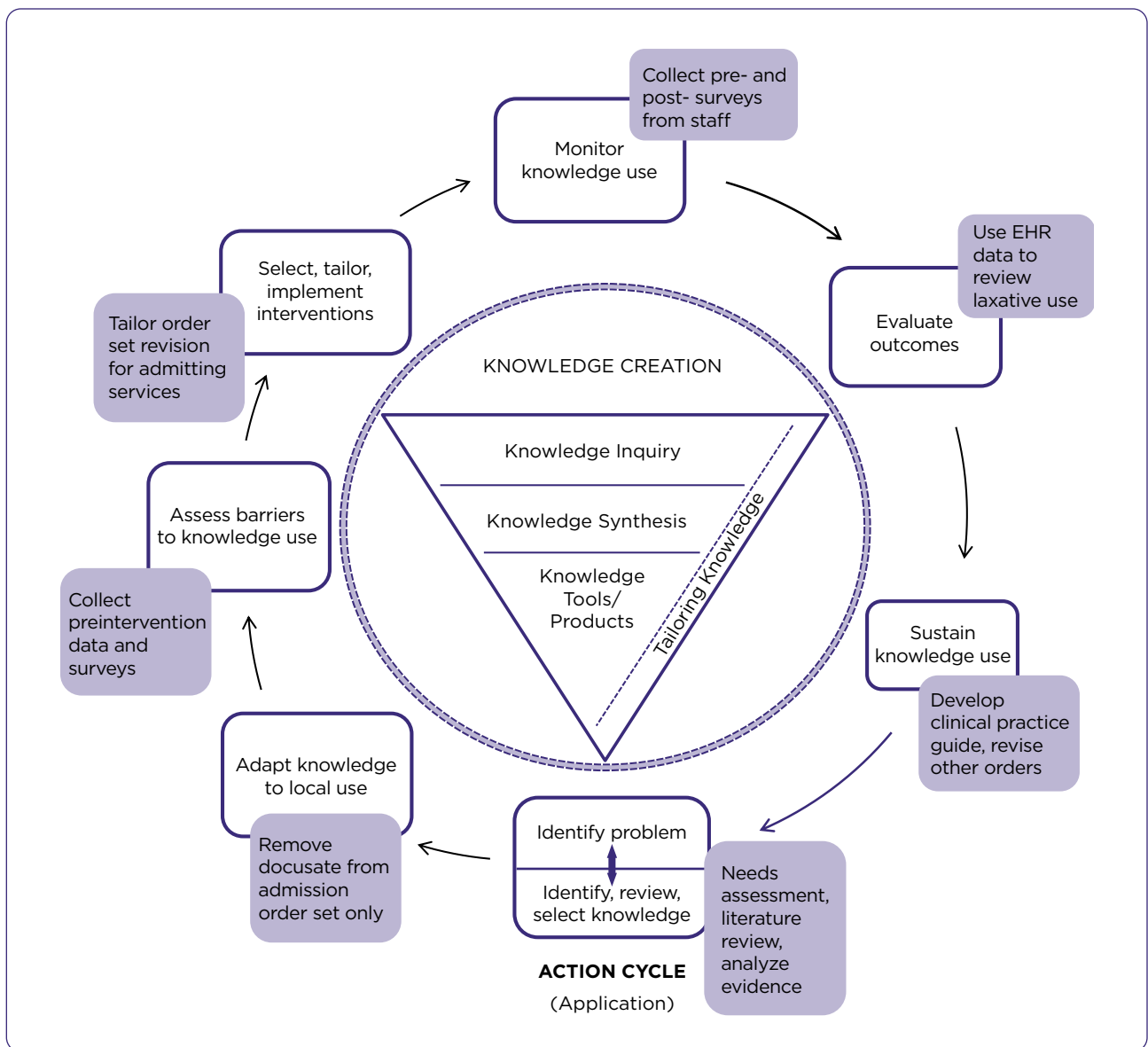


Figure 1. Conceptual framework: The knowledge to action framework. Adapted from Graham et al. (2006).

quality of bowel movements into the EMR. This site has a robust palliative care consult service and when involved in a patient's care, these consultants provide recommendations for the management of OIC, relying on the primary team to enter the orders.

Included in this project were inpatient adult admitting services. At this cancer center, each admitting service has its own unique order set. Hospital admitting services were invited to participate in the revision of the standard admission order set by email and in-person conversations. Critical care areas and gastrointestinal surgery services were excluded. A total of 38 unique admission order sets were identified. Five order sets were excluded for various reasons: (1) inclusion criteria, (2) order set owners could not be identified, or (3) order set was not in use. An email invitation to participate with a brief description of the project and an infographic (Appendix A) was sent to the division chiefs of the admitting team and the order set owner. Division leaders and order set owners informed the project leader of their decision about participation by responding to the email. Out of the 33 eligible unique admission order sets, 18 agreed to participate in the revision. Admitting services who did not participate in the revision did not experience any change to standard of care. This project was exempt from Institutional Review Board (IRB) review.

To carry out the order set revision, the project leader collaborated with informatics staff to identify the order sets and carry out three tasks: (1) remove docusate from the available options of laxatives in the order set, (2) add polyethylene 17 g by mouth once daily as needed, and (3) add senna 2 tabs by mouth nightly, standing. The workflow for editing the order sets is shown in Figure 2. An email describing the project was sent to members of the participating services, who also received education in person or virtually. The infographic was printed and placed on units where the revised order sets were commonly used. Key stakeholders from the hospital's palliative care service acted as mentors. Importantly, use of the admission order sets was not mandatory. Prescribers were able to enter orders for any laxative (including docusate) at the dose/frequency desired.

To understand the impact of these order set changes on patient care, variables were collected from the EMR retrospectively. The primary outcomes were the number of docusate, senna, and polyethylene glycol, and other laxative orders entered for admitted patients who were prescribed an opioid medication. The frequency of docusate prescriptions at discharge was also collected. Laxatives were categorized by drug class: stimulant laxatives (senna, docusate-senna, bisacodyl), osmotic laxatives (lactulose, milk of magnesia, magnesium citrate, magnesium hydroxide, phosphate), suppositories (bisacodyl, glycerin), bulking agents (psyllium, methylcellulose), and medications for laxative refractory OIC, called functional bowel disorder medications (methyl-naltrexone, naloxegol, alvimopan, lubiprostone, and linaclotide). Orders for docusate were counted only if the single agent, not docusate-senna, was ordered. Secondary outcomes included incidence of OIC, length of stay, presence of inpatient palliative care consultation, and admission for OIC complications. International Classification of Diseases (ICD)-10 codes were used to capture incidence of OIC and complications of OIC (ileus, bowel obstruction, or abdominal pain) at any point during patients' admission.

Data Collection and Analysis

Deidentified data was collected from the EMR. Data on unique admissions 6 weeks before (April 4 to May 15, 2021) and 6 weeks after (July 26 to September 6, 2021) the intervention were selected for extraction. Six weeks was deemed a reasonable amount of time to capture any variances in prescribing. Outcomes were assessed using descriptive statistics. Tests for normality were calculated, including Kolmogorov-Smirnov and Shapiro-Wilk tests. The data did not have a normal distribution and required the use of non-parametric tests for continuous variables (e.g., age, length of stay). Measures of central tendency, frequencies, and measures of dispersion were collected to summarize and describe the data at baseline and after the intervention. Chi-squared test, Phi and Cramer's V were used to analyze nominal data. Data was analyzed using SPSS (version 28). A *p* value of less than .05 was used to define statistical significance.

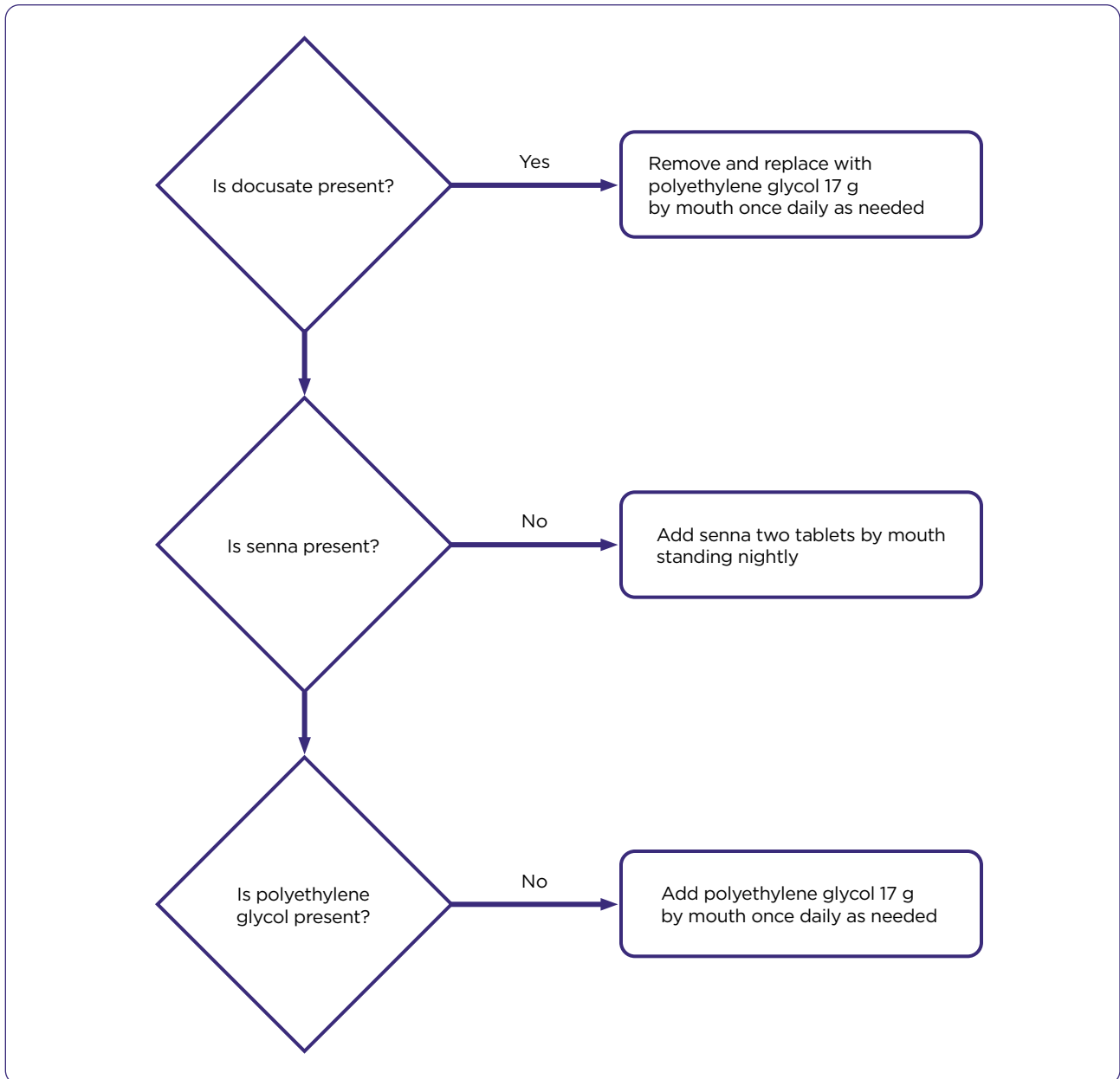


Figure 2. Workflow for laxative order set changes.

RESULTS

Demographics

A total of 2,742 patient admissions preintervention was compared to 2,752 admissions postintervention to evaluate the effects of the revision of laxatives in the standard admission order set. There were no significant differences in age or sex between the pre- and postintervention groups ($p = .132$, $p = .789$, respectively). Out of the entire cohort, most patients (74%) had cancers of multiple

primaries (two or more separate neoplasms), cancers of the digestive system, or breast cancer. Cancer diagnoses were based on Surveillance, Epidemiology, and End Results (SEER) classifications in which multiple primaries may also indicate cancer of single primary with metastatic disease (Table 1).

Laxative Prescribing

Most (53%) laxative orders were entered prophylactically (within 24 hours of the opioid order).

Table 1. Demographic and Clinical Characteristics^a (N = 5,494)

Characteristic	Preintervention, n (%)	Postintervention, n (%)	p value
Age (years), mean, range	62 (18–97)	61 (18–96)	.132
Sex			
Female	1,410 (51)	1,395 (51)	.789
Male	1,342 (49)	1,347 (49)	
Cancer type			
Multiple primaries ^b	1,584 (56)	1,425 (52)	
Digestive	799 (14)	410 (15)	
Respiratory	230 (4)	131 (4)	
Breast	232 (4)	125 (4)	
Constipation diagnosis	505 (18)	283 (10)	< .001
OIC diagnosis	174 (6)	51 (2)	< .001
Palliative care encounter	362 (13)	319 (12)	.087
Admission for bowel problems ^c	339 (12)	343 (12)	.910
Length of stay (days), mean, range	27 (1–61)	27 (1–61)	.719

Note. OIC = opioid-induced constipation.
^aThe sample median (minimum, maximum) is given for continuous variables. A *p* value of less than .05 was used to define statistical significance.
^bCancer diagnoses were collected using SEER classification. Multiple primaries may include those with single primary and metastatic disease.
^cOIC complications include ileus, bowel obstruction, or abdominal pain.

The number of orders for docusate and docusate-senna decreased significantly ($p < .001$; $p = .002$, respectively) after the order set modification. However, the number of orders for polyethylene glycol, senna, other laxatives, or functional bowel disorder medications did not change significantly (all $p > .05$). There were no significant changes in the frequency of prescriptions for docusate ($p = .104$) or other laxatives ($p = .104$) at discharge. A summary of laxative prescribing pre- and postintervention are in Table 2.

Secondary Outcomes

The frequency of OIC diagnoses decreased significantly after the intervention ($p < .001$ and $p < .001$ respectively). There was no significant difference in the number of patients admitted due to bowel-related complications (abdominal pain, bowel obstruction, or ileus; $p = .910$). Hospital length of stay ranged from 1 to 61 days ($M = 27$, $SD = 19$), and there was no significant difference noted after the intervention ($p = .719$). No significant difference was observed in the number of patients who received a palliative care consultation ($p =$

.087). These results are shown in Table 1. The three most frequently used admission order sets were for gastrointestinal oncology medicine ($n = 617$, 11.2%), head, neck, and melanoma ($n = 277$, 5.0%), and thoracic medicine ($n = 240$, 4.4%) admitting services.

DISCUSSION

This report found that a modification to an admission order set in the EMR was a feasible approach to improve guideline-concordant laxative prescribing for hospitalized adults who are on opioid therapy. A revision to the laxative options in the admission order sets at this dedicated cancer center led to a significant reduction in the number of orders for docusate and the combination laxative docusate-senna. In addition, there was a significant reduction in the number of patients diagnosed with constipation or OIC after the intervention. This admission order set revision also served as an opportunity to provide education on the prevention and management of OIC.

Although there were no significant changes in the number of orders for polyethylene glycol, senna, or other laxatives, it is possible the prescribers

Table 2. Summary of Laxative Prescribing

	Pre-intervention, <i>n</i> (%)	Post-intervention, <i>n</i> (%)	Total, <i>n</i> (%)	<i>p</i> value ^a
<i>Admission orders</i>				
Docusate				
No	1,456	1,296	3,039	< .001
Yes	1,583	1,159	2,455	
Polyethylene glycol				
No	1,993	2,005	3,998	.559
Yes	759	737	1,496	
Senna				
No	1,706	1,680	3,386	.582
Yes	1,046	1,062	2,108	
Docusate-senna				
No	2,705	2,721	5,426	.002
Yes	47	21	68	
Other laxatives ^a				
No	2,123	2,151	4,274	.245
Yes	629	591	1,220	
Functional bowel disorder medications ^b				
No	2,537	2,540	5,077	.533
Yes	215	202	417	
Prophylactic laxative orders ^c				
No	1,479	1,446	2,925	.454
Yes	1,273	1,296	2,569	
<i>Discharge orders</i>				
Any laxative				
No	1,899	853	2,752	.104
Yes	1,836	906	2,742	
Docusate				
No	1,899	1,836	3,735	.104
Yes	853	906	1,759	

Note. ^a*p* value of less than .05 was used to define statistical significance.

^bOther laxatives include bisacodyl, lactulose, milk of magnesia, magnesium citrate, magnesium hydroxide, phosphate, suppositories (bisacodyl, glycerin), bulking agents (psyllium, methylcellulose).

^cFunctional bowel disorder medications include methylnaltrexone, naloxegol, alvimopan, lubiprostone, and linaclotide.

^dLaxative orders were placed within 24 hours of the opioid order.

were already utilizing these medications effectively. These findings could be explained by the lack of “hard stops” for laxative orders when prescribing an opioid. While prescribers have the option to select the medications available in the admission order sets, it is not mandatory. The use of electronic “hard stops” or “nudges” has not been well studied for laxative prescribing for OIC (Edrees et

al., 2020). Still, the EMR is a common vehicle to implement change in practice, specifically to order sets because they are a valued convenience for hospital prescribers.

A similar intervention was done in a Canadian hospital where docusate was removed from the admission order set and other laxative options were added for patients admitted to the

hematology-oncology unit (von Maltzahn et al., 2022). This resulted in a 35% reduction of docusate prescriptions and no change in the overall rate of treatment of constipation. Other studies have also reported on the successful uses of EMR-based interventions to reduce inappropriate laxative prescribing for OIC. Chineke and colleagues (2020) utilized the EHR to create a new progress note template, which included a mandatory section for providers to document pain and constipation that led to improved documentation of constipation management. Lucy and colleagues (2024) developed a new constipation prevention and management order set that excluded docusate as an option and paired it with education targeted to hospital teams with the highest number of docusate orders. Increasing the visibility of laxative options in the EMR has also shown to be useful in improving laxative co-prescribing for hospitalized older adults (Liu et al., 2020). The addition of a process-related barrier, such as having a pharmacist call the prescriber of docusate and provide education before approving the order, has also shown to be successful in reducing inappropriate use of docusate (Shair et al., 2023).

Management of OIC can be challenging because all patients on an opioid regimen are at risk of developing this side effect. Reports have shown that prescribers—physicians and APPs—want guidance on the prevention and management of OIC. A survey of 73 residents and attending physicians found most (63%) favored the use of a protocol for laxative prescribing as part of an admission order set, and the majority (79%) were in favor of a protocol for prescribing laxatives at discharge (Moore et al., 2019). Prescribers need education and convenient ways to apply evidence-based approaches to care. Use of a constipation management algorithm has been studied in several quality improvement projects, resulting in guideline-concordant laxative use and decreased incidence of constipation when bundled with prescriber and patient education, and/or auditing (Lipshaw et al., 2021; Van Orne, 2021; Davies et al., 2023). With this project, more than half (54%) of the existing order sets were included, of which prescribers were provided with education (Appendix A) on appropriate laxative prescribing. A clinical decision tool or algorithm embedded in the EMR can be a future approach to disseminate

knowledge to those not included in this project and sustain practice change.

Reducing the use of ineffective agents (docusate) and optimizing other laxatives (stimulants and osmotics) has the potential to reduce hospital length of stay, overall costs of care, and number of urgent care visits. Prescribers, both physicians and APPs alike, can lead through example by using effective laxative regimens to prevent and manage OIC, direct quality improvement or quality assurance approaches, or conduct research on this topic. Future research observing costs associated with purchasing and dispensing docusate, along with nursing hours directed to administration, can be informative for systems-based interventions. Economic studies on health-care utilization for constipation-related problems may further inform interventions to prevent and manage OIC effectively. Additional research on the sustainability of EMR interventions to improve laxative prescribing for OIC and the use of novel agents for laxative refractory OIC is warranted.

Limitations

This project had several limitations. Despite recruitment efforts, only half of the existing order sets were included in the revision. Services that agreed to participate may have already been prescribing laxatives per guideline recommendations. The retrospective nature of data collection was dependent upon documentation in the EMR, and as such, it was difficult to determine the reasons for docusate use (e.g., patient requested docusate vs. prescriber preference). The use of ICD-10 codes to capture admission reason related to bowel complications may have limited the accuracy of this outcome.

CONCLUSION

Opioid-induced constipation is a common adverse effect experienced in patients with a diagnosis of cancer on opioid therapy and contributes to the physical, emotional, and functional burdens of this patient population. Appropriate prevention and management of OIC is essential to comprehensive cancer management and to maintain an acceptable quality of life. There is an overuse of stool softeners for the management of OIC, which can delay the use of more effective agents. Current international and national guidelines do

not recommend the use of stool softeners such as docusate to prevent and manage OIC. A revision to the laxative options in a standard admission order set is a feasible method to improve the prevention and management of OIC. The removal of docusate from a selected number of admission order sets led to a significant reduction of docusate orders. Methods to increase the use of osmotic and stimulant laxatives require different quality improvement approaches. Further interventions to align practice with national and international standards on appropriate prescribing for adult cancer patients with OIC are warranted. ●

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IMPROVING THE PREVENTION AND MANAGEMENT OF OPIOID INDUCED CONSTIPATION (OIC)

90%

of cancer patients require opioids for pain management

86%

of patients with cancer have OIC

87%

of cancer patients on opioids receive inadequate laxatives

OIC is a side effect that persists without tolerance

EFFECTS OF OIC: MULTIDIMENSIONAL BURDENS

Physical

- Abdominal pain
- Bowel obstruction
- Fecal impaction

Economic

- Increased health care utilization
- Higher overall costs of care

Quality of Life

- Negative effects on function
- Negative emotions and thoughts

EVIDENCE BASED LAXATIVE SELECTION

Laxatives are the first line intervention for prevention and management of OIC

Few cancer organizations recommend the use of docusate for prevention and management of OIC

- Avoid docusate
- Use stimulant laxatives *senna, bisacodyl*
- Use osmotic laxatives *polyethylene glycol, lactulose, magnesium citrate*

A CHANGE TO THE LAXATIVES AVAILABLE IN THE ADMISSION ORDER SET

Bowel Regimens:

- Bisacodyl - 5 mg tablet EC
Dose: 5 mg oral, Routine
- Docusate Sodium - 100 mg capsule
Dose: 100 mg oral tid, Routine
- Magnesium Citrate - 17.5 Gm /300 mL Bottle liquid
Dose: 300 ml oral once, Routine
- Magnesium Citrate is a saline laxative
- Polyethylene Glycol 3350 - 17 gm packet powder
Dose: 17 gm oral daily, Routine
- Dissolve 1 packet (17gms) in 8 ounces of water, juice, soda, coffee or tea.
- Lactulose - 30 mL solution
Dose: 30 ml oral daily PRN constipation, Routine
- Senna - 8.6 mg tablet
Dose: 2 tablet oral bedtime nightly, Routine
- Magnesium Hydroxide - 400 mg/5 mL suspension
Dose: 30 ml oral q8h PRN constipation, Routine, Max Daily Dose: 60 mL
Max Daily Dose= 60 mL

ORDER SET CHANGES:

- Removal of docusate
- Keep/Add polyethylene glycol 17g by mouth once daily as needed
- Keep/Add senna two tablets by mouth standing nightly

Please note: Docusate can still be ordered

Appendix A. Improving the prevention and management of opioid-induced constipation.