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QUALITY IMPROVEMENT

Fostering Oral Chemotherapy Understanding and Safety (FOCUS) Project: Interventions for Improving Knowledge and Compliance With National Safety Standards

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Abstract

Background: Oral chemotherapy drug development and use has increased, and evidence in the literature suggests variability in practices nationally. Thus, there is a need for continuous review of the process of oral chemotherapy administration that focuses on improving adherence to national standards. **Objectives:** This quality improvement project evaluated provider and staff general knowledge on oral chemotherapy and national safety standards and the implementation and ease of use of an electronic medical record (EMR)-integrated chemotherapy documentation template geared toward improving compliance with national chemotherapy administration standards. **Methods:** This project utilized a pre-test and post-test design comparing provider and staff knowledge as well as the intervention of a chemotherapy documentation template to assess compliance with national chemotherapy administration safety standards in an academic medical center. Through chart review, 24 national safety standards relevant to oral chemotherapy administration were used to assess compliance prior to and following the introduction of the intervention. Additionally, feasibility, accessibility, and usability of the intervention were evaluated through a validated questionnaire. **Findings:** Knowledge gained from pre-test to post-test improved (p value of < .001). Additionally, from the 88 charts reviewed, there was a statistical improvement in compliance with national safety standards (p value of < .001). The participants (n = 29) scored the documentation template as above average, indicating overall ease of use and feasibility for continued use.

The use of oral chemotherapy (also known as oral anticancer therapies) has grown exponentially, and the number of cancer patients receiving oral chemotherapy is steadily increasing (Solomon et al., 2019). With over 25 million doses administered annually, oral chemotherapy is a potentially hazardous treatment for cancer patients (Weingart et al., 2012). Despite the development of national administration safety standards by the Oncology Nursing Society (ONS) and the American Society of Clinical Oncology (ASCO; Neuss et al., 2016), variations in practice have remained a common theme in previously published reviews of the current state of quality and safety in oral chemotherapy (Krzyzanowska & Powis, 2015). Moreover, little is known about the application of the standards to the administration of oral anticancer therapies in general practice (LeFebvre & Felice, 2016).

In 2016, the American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) updated their standards for the safe administration of chemotherapy (Neuss et al., 2016). These standards provide a framework for oncology practices to implement policies and procedures, and internal quality assessment and monitoring. In addition, these standards were adopted for third-party safety assessments that are used by the ASCO Quality Oncology Practice Initiative (QOPI) (LeFebvre & Felice, 2016). The QOPI standards focus on three primary areas for oral chemotherapy: education, documentation, and monitoring (Mulkerin et al., 2016). However, oncology practices and centers are not required to obtain QOPI certification (Dreyfuss, 2010). Consequently, there are variations in documentation, education, and monitoring practices, specifically as it relates to oral chemotherapy.

Observational studies show that safety practices regarding the prescription of oral chemotherapy vary widely across cancer centers in the United States, with approximately half reporting having no safeguards at all for writing prescriptions (Greer et al., 2014). Among National Cancer Institute–designated cancer centers, only 40% provide oral chemotherapy-specific educational materials, and documentation of oral chemotherapy monitoring is nonuniform (Weingart et al., 2011). A review of the literature indicates that improvements in compliance to oral chemotherapy safety standards are still an ongoing opportunity with no clear established standard of practice in the United States (Solomon et al., 2019). However, one common recommendation seen was in the enhanced use of electronic medical record (EMR) systems to improve compliance with safety standards. Therefore, this quality improvement (QI) project focused on leveraging the use of the EMR to increase compliance with national chemotherapy administration safety standards through the implementation of a documentation template.

METHODS

Design/Setting/Framework

This QI project utilized a pre-test and post-test intervention design and was implemented at an ambulatory outpatient cancer center. The framework used in this project was the Pronovost model for large scale knowledge translation (Pronovost et al., 2008). This framework embeds an explicit method for knowledge translation in a collaborative model for broader dissemination of knowledge into practice (Pronovost et al., 2008). It includes five key components: 1) A focus on systems rather than the care of the individual, 2) Engagement of local interdisciplinary teams to assume ownership of the improvement project, 3) Creation of a centralized support for technical work, 4) Encouraging adaptation of the intervention, and 5) Creating a collaborative culture within the local unit and larger system.

Aims/Instruments/Data Collection

This QI project had three aims.

Aim 1 was to educate stakeholders on the national chemotherapy safety standards by administering a pre-test, then providing an educational session, followed by a post-test. An instrument assessing knowledge was developed that established face validity with a construct, and test construct expert and content was validated by two content experts. This instrument included a combination of 14 multiple choice and true or false questions and was administered to providers and staff who are involved in the care of a patient on an oral oncologic treatment. The educational session was then delivered virtually. Following the educational session,

a post-test (using the same instrument) was administered to the same providers and staff who took the pre-test and attended the educational session. A paired *t*-test was used to compare pre- and post-exam scores.

Aim 2 was to determine the impact of a chemotherapy documentation template within the EMR on national chemotherapy safety standards within a 12-week period. An initial chart review (from an EMR report that included patients 18 years of age or older with a diagnosis of cancer and on an oral chemotherapy treatment) was performed on 44 patients to obtain baseline data on the project site's overall compliance to national safety standards. Following this, a new chemotherapy documentation template was introduced that pulled in populated discrete information within the EMR and included relevant 24 safety standards. A post-intervention chart review of a different set of 44 patients was then performed to evaluate compliance with use of the template. The safety standards evaluated for each patient mimicked previously utilized mock tracer audits for accreditation surveys by the site and from similar studies (Zhu et al., 2015; Mackler et al., 2018; Zerillo et al., 2015; & McNamara et al., 2016) that utilized ASCO QOPI measures for QI projects surrounding compliance with oral chemotherapy. An independent *t*-test was conducted and the difference in scores from pre-intervention to post-test was used to analyze the results.

Aim 3 of the project was to determine the feasibility, usability, and acceptability of the documentation template by administering the System Usability Scale (SUS) questionnaire (Brooke, 1996) to participants at the project site post intervention. This questionnaire includes 10 questions on a Likert scale from strongly disagree to strongly agree and a comment section for qualitative feedback. It has a global reliability of 0.92 and construct reliability of 0.91. Its subconstructs are usability and learnability (Sauro, 2015). It is the most frequently used questionnaire to measure perceived usability across products and websites (Sauro, 2015). It has been tested in this population but not specifically on the subject of oral chemotherapy. Results were analyzed using the validated scoring guideline.

RESULTS

Aim 1: Knowledge Gained

This QI project was conducted from August 2021 to December 2021. 126 participants were initially identified, and a pre-test was administered electronically. 92 participants took the pre-test. The 92 participants were then invited to attend a virtual educational session that lasted 30 minutes. 42 of the 92 participants attended the live virtual educational session. The recording of the session and educational materials were immediately sent to the remaining participants who could not attend. Following the educational session, a post-test was administered electronically, which 65 participants completed (Table 1). The highest participation came from nurse practitioners (64.1%). The pre-test mean percent score was 42.9% (standard deviation [SD], 10.2), and the post-test mean percent score significantly improved to 54.0% (SD, 20.8), $p < .001$.

Aim 2: Impact of a Chemotherapy Documentation Template in the EMR

Forty-four patient charts were reviewed before the intervention and another set of 44 patient charts were reviewed post intervention. Both samples consisted of an older patient population with a mean age of 68.3 (pre-intervention group) and 65.0 years (post-intervention group). Male gender, White race, and the diagnosis of a solid tumor malignancy characterized the majority of both groups.

There were 24 chemotherapy safety standards reviewed (Appendix A) that were pertinent to oral chemotherapy. One point was allocated for each standard met. The mean number of points in the pre-intervention group that met standards was 12.0 with an SD of 4.1. In the post-intervention

Table 1. Participants in Knowledge Assessment

Role, *n (%)*	Pre-test	Post-test
Clinical pharmacist	9 (9.8%)	6 (9.2%)
Nurse	17 (18.5%)	12 (18.5%)
Nurse practitioner	59 (64.1%)	40 (61.5%)
Physician	2 (2.2%)	2 (3.1%)
Physician assistant	5 (5.4%)	5 (7.7%)
Total	92 (100.0%)	65 (100.0%)

group, the mean number points that met standards was 22.8 with an SD of .78. Utilizing an independent *t*-test, the mean difference in scores from the pre-intervention group to post-intervention group, was –10.750 with a *p* value of < .001.

Aim 3: Feasibility, Usability, and Acceptability of the Chemotherapy Documentation Template

A total of 29 providers who used the template completed the SUS survey: 23 nurse practitioners 79.3%, five physician assistants (17.3%), and one physician (3.4%). The mean SUS score was 75.5 with a median of 80, an above-average score, according to survey grading guidelines. Common positive themes were that the chemotherapy documentation template was easy and simple to use, and providers voiced the importance of documentation to improve patient safety. Other themes illustrated the need to incorporate disease-specific documentation and improving the length of time it took to fill out the information.

DISCUSSION

This QI project provided an opportunity to leverage the use of the EMR to have a standardized approach to documentation of areas like patient consent and education, which significantly improved compliance with ASCO QOPI and ASCO/ONS chemotherapy administration safety standards and can be applied in any setting. Moreover, it included two other aims not addressed in literature that encompasses assessment of provider knowledge and feasibility, usability, and acceptability of the intervention.

Strengths

A major strength of this QI project was the large sample of providers and staff who participated in this QI project. Many of the participants were advanced practitioners (APs), which was essential given their critical role in cancer patient treatment education and monitoring. Furthermore, several evaluations were performed that applied to a real-world clinical scenario that can be applied to other practice settings. Lastly, the goal was to not impact current workflows and replicate the workflows created for intravenous chemotherapy, which created awareness among providers regarding the safety of both modes of administration.

Limitations

The major limitation to this project was that it was conducted during the COVID-19 pandemic, which limited recruitment of a more diverse provider and staff population due to staffing shortages. It was also what likely contributed to the high attrition of participants from pre- to post-test. Due to reduced information technology resources, it was also difficult to troubleshoot issues when the project launched due to competing priorities with other health system COVID-19 initiatives. As a result, one of the standards was not added in time to the documentation template, which caused < 100% compliance rates in the post-intervention group. Furthermore, this project did not address adherence, which is a component of monitoring patients on oral chemotherapy. The outcome of this project focused on documentation of relevant standards. As a result, further analysis is needed if compliance with documentation of national safety standards led to improvement in patient outcomes and safety.

CONCLUSION

To address the increased use of oral treatments in cancer and provide safe and quality care that aligns with national chemotherapy safety guidelines, a multidisciplinary approach and standardized process within practice is needed. Additionally, leveraging the use and functionality of the EMR can positively impact safe practices in achieving compliance with national safety standards. This project also highlights the important role that APs play in the oral chemotherapy administration process and demonstrates that more provider/staff awareness and education is needed. This is a critical component in which focus should be priority and would provide better understanding of the demand to meet national standards of practice, which ultimately impacts patient outcomes. Future directions will include evaluating more in depth the impact of the role of the AP in oral chemotherapy adherence and outcomes.

Disclosure

The authors have no conflicts of interest to disclose.

References

American Society of Clinical Oncology. (2023). About QOPI Certification. https://old-prod.asco.org/practice-patients/quality-improvement/quality-programs/qopi-certification-program/about-qopi

Brooke, J. (1996). SUS: A quick and dirty usability scale. *Usability Evaluation in Industry, 189*(194), 4-10.

Dreyfuss, J. H. (2010). New joint outpatient chemotherapy administration standards. *CA: A Cancer Journal for Clinicians, 60*(2), 66–67. https://doi.org/10.3322/caac.20065

Greer, J. A., Lennes, I. T., Gallagher, E. R., Temel, J. S., & Pirl, W. F. (2014). Documentation of oral versus intravenous chemotherapy plans in patients with metastatic non-small-cell lung cancer. *Journal of Oncology Practice, 10*(2), e103–e106. https://doi.org/10.1200/JOP.2013.001154

Krzyzanowska, M. K., & Powis, M. (2015). Extending the quality and safety agenda from parenteral to oral chemotherapy. *Journal of Oncology Practice, 11*(3), 198–201. https://doi.org/10.1200/JOP.2015.004002

LeFebvre, K. B., & Felice, T. (2016). Nursing application of oral chemotherapy safety standards: An informal survey. *Clinical Journal of Oncology Nursing, 20*(3), 258–262. https://doi.org/10.1188/16.cjon.258-262

Mackler, E., Scappaticci, G. B., Salgado, T. M., Petersen, L., Davis, E. J., Peltier, E.,...Farris, K. B. (2018). Impact of a statewide oral oncolytic initiative on five participating practices. *Journal of Oncology Practice, 14*(5), e304–e309. https://doi.org/10.1200/JOP.18.00058

McNamara, E., Redoutey, L., Mackler, E., Severson, J. A., Petersen, L., & Mahmood, T. (2016). Improving oral oncolytic patient self-management. *Journal of Oncology Practice, 12*(9), e864–e869. https://doi.org/10.1200/JOP.2016.011304

Mulkerin, D. L., Bergsbaken, J. J., Fischer, J. A., Mulkerin, M. J., Bohler, A. M., & Mably, M. S. (2016). Multidisciplinary optimization of oral chemotherapy delivery at the University of Wisconsin Carbone Cancer Center. *Journal of Oncology Practice, 12*(10), e912–e923. https://doi.org/10.1200/JOP.2016.013748

Neuss, M. N., Gilmore, T. R., Belderson, K. M., Billett, A. L., Conti-Kalchik, T., Harvey, B. E.,...Polovich, M. (2016). 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. *Oncology Nursing Forum, 44*(1), 31–43. https://doi.org/10.1200/JOP.2016.017905

Pronovost, P. J., Berenholtz, S. M., & Needham, D. M. (2008). Translating evidence into practice: A model for large scale knowledge translation. *BMJ, 337*, a1714. https://doi.org/10.1136/bmj.a1714

Sauro, J. (2015). SUPR-Q: A comprehensive measure of the quality of the website user experience. *Journal of Usability Studies, 10*(2), 68–86. https://uxpajournal.org/supr-q-a-comprehensive-measure-of-the-quality-of-the-website-user-experience/

Solomon, J. M., Ajewole, V. B., Schneider, A. M., Sharma, M., & Bernicker, E. H. (2019). Evaluation of the prescribing patterns, adverse effects, and drug interactions of oral chemotherapy agents in an outpatient cancer center. *Journal of Oncology Pharmacy Practice, 25*(7), 1564–1569. https://doi.org/10.1177/1078155218798150

Weingart, S. N., Li, J. W., Zhu, J., Morway, L., Stuver, S. O., Shulman, L. N., & Hassett, M. J. (2012). US Cancer Center Implementation of ASCO/Oncology Nursing Society Chemotherapy Administration Safety Standards. *Journal of Oncology Practice, 8*(1), 7–12. https://doi.org/10.1200/JOP.2011.000379

Weingart, S. N., Spencer, J., Buia, S., Duncombe, D., Singh, P., Gadkari, M., & Connor, M. (2011). Medication safety of five oral chemotherapies: a proactive risk assessment. *Journal of Oncology Practice, 7*(1), 2–6. https://doi.org/10.1200/JOP.2010.000064

Zerillo, J. A., Pham, T. H., Kadlubek, P., Severson, J. A., Mackler, E., Jacobson, J. O., & Blayney, D. W. (2015). Administration of oral chemotherapy: Results from three rounds of the quality oncology practice initiative. *Journal of Oncology Practice, 11*(2), e255–e262. https://doi.org/10.1200/JOP.2014.001842

Zhu, J., Zhang, T., Shah, R., Kamal, A. H., & Kelley, M. J. (2015). Comparison of Quality Oncology Practice Initiative (QOPI) Measure Adherence Between Oncology Fellows, Advanced Practice Providers, and Attending Physicians. *Journal of Cancer Education, 30*(4), 774–778. https://doi.org/10.1007/s13187-015-0798-z

Appendix A. ASCO/ONS Chemotherapy Administration and ASCO QOPI Standards Used

Number	Domain area	Domain	ASCO/ONS standard	ASCO QOPI standard #
1	Creating a Safe Environment: Chart documentation before first administration	1.5.1	Pathologic confirmation or verification of initial diagnosis.	1.2.1
2	Creating a Safe Environment: Chart documentation before first administration	1.5.2	Initial cancer stage, or current cancer status.	1.2.2
3	Creating a Safe Environment: Chart documentation before first administration	1.5.3	Complete medical history and physical examination.	1.2.3
4	Creating a Safe Environment: Chart documentation before first administration	1.5.3	Pregnancy status, as applicable.	1.2.4
5	Creating a Safe Environment: Chart documentation before first administration	1.5.4	Presence or absence of allergies and history of hypersensitivity reactions.	1.2.5
6	Creating a Safe Environment: Chart documentation before first administration	1.5.5	Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and treatment plan.	1.2.6
7	Creating a Safe Environment: Chart documentation before first administration	1.5.6	Initial psychosocial assessment, with action taken when indicated.	1.2.7
8	Creating a Safe Environment: Chart documentation before first administration	1.5.7	The chemotherapy treatment plan, including at minimum, the patient diagnosis, drugs, doses, duration or treatment, and goals of therapy.	1.2.8
9	Creating a Safe Environment: Chart documentation before first administration	1.5.8	Planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy agent(s).	1.2.9
10	Treatment Planning, Patient Consent, and Documentation	2.2	Informed consent and assent (optional) for chemotherapy treatment, as appropriate to the treatment population, is documented bedore initiation of a chemotherapy regimen.	2.1
11	Treatment Planning, Patient Consent, and Documentation	2.3	Patients are provided with verbal and written of electronic information as part of an education process before the first administration of treatment of each treatment plan.	2.2
12	Treatment Planning, Patient Consent, and Documentation	2.3	The content of this educational material will be documented. Educational information includes the following minimum.	2.2.2
13	Treatment Planning, Patient Consent, and Documentation	2.3.1	Patient's diagnosis.	2.2.3.1
14	Treatment Planning, Patient Consent, and Documentation	2.3.2	Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.	2.2.3.2
15	Treatment Planning, Patient Consent, and Documentation	2.3.3	Planned duration of treatment, schedule of treatment administration, drug names and supportive medication, drug-drug and drug-food interactions, and plan for missed doses.	2.2.3.3 and 2.2.3.4

Note. Information from ASCO (2023) and Neuss et al. (2016).

Appendix A. ASCO/ONS Chemotherapy Administration and ASCO QOPI Standards Used (cont.)

Number	Domain Area	Domain	ASCO/ONS Standard	ASCO QOPI Standard #
16	Treatment Planning, Patient Consent, and Documentation	2.3.4	Potential long-term and short-term adverse effects of therapy, including infertility risk for appropriate patients.	2.2.3.5
17	Treatment Planning, Patient Consent, and Documentation	2.3.5	Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate attention.	2.2.3.6
18	Treatment Planning, Patient Consent, and Documentation	2.3.6	Symptoms or events that require immediate discontinuation of oral or other self-administered treatments.	2.2.3.6
19	Treatment Planning, Patient Consent, and Documentation	2.3.7	Procedures for handling medications in the home, including storage, safe handling, and management of unused medication.	2.2.3.7
20	Treatment Planning, Patient Consent, and Documentation	2.3.8	Procedure for handling body secretions and waste in the home.	2.2.3.8
21	Treatment Planning, Patient Consent, and Documentation	2.3.9	Follow-up plans, including laboratory and provider visits.	2.2.3.9
22	Treatment Planning, Patient Consent, and Documentation	2.3.10	Contact information for the health care setting, with availability and instructions on when and who to call.	2.2.3.10
23	Treatment Planning, Patient Consent, and Documentation	2.3.11	Expectations for rescheduling or cancelling appointments.	2.2.3.11
24	Treatment Planning, Patient Consent, and Documentation	2.4	Education includes family, caregivers, or others on the basis of the patient's ability to assume responsibility for managing therapy. Educational activities will be performed on the basis of the patient's learning needs, abilities, preferences, and readiness to learn.	2.2.1

Note. Information from ASCO (2023) and Neuss et al. (2016).