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QUALITY IMPROVEMENT

Evaluating the Impact of a Clinical Pharmacist in Patients Receiving New Chemotherapy for Breast Cancer: Analysis of a Pilot Study

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

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Abstract

Purpose: Breast cancer treatment may include chemotherapy, which is associated with significant toxicities. At the Sidney Kimmel Cancer Center at Jefferson Health, a pilot program was developed to add an oncology clinical pharmacist to the breast cancer clinic. The purpose of this study is to identify the impact of the clinical pharmacist in supportive care management, add to existing literature discussing the impact of the clinical pharmacist in ambulatory oncology settings, and justify future, permanent ambulatory oncology pharmacist positions within the institution. **Methods:** This single-center retrospective chart review assesses interventions made by the clinical pharmacist in patients with any stage of breast cancer who presented to the breast clinic for new chemotherapy treatment between September 1, 2020, and February 28, 2021. The primary outcome was to describe clinical pharmacist interventions at the first follow-up encounter after chemotherapy initiation. Secondary outcomes included classifying and quantifying total interventions and comparing intervention details between total and included patients within the 6-month timeframe. **Results:** Of 44 included patients, 29 had a follow-up encounter. The clinical pharmacist directly managed 33% of the 58 patient-reported adverse drug effects. In 6 months, the clinical pharmacist made 1,068 interventions spanning 189.6 documented hours. The most common interventions were coordination of care, education, and supportive care pharmacotherapy interventions. **Conclusion:** This study identified the pharmacist's role in supportive care management and reports the successful integration of a clinical pharmacist into a breast cancer clinic. Future directions include conducting prospective studies to further explore the impact of the clinical pharmacist on treatment outcomes.

Breast cancer is the second most common malignancy among women in the United States. Approximately 13% of women in the United States will develop breast cancer in their lifetimes, and an estimated 43,250 will die from breast cancer each year (SEER*Explorer, 2023). Breast cancer treatment may include chemotherapy, which is associated with significant cardiac, gastrointestinal, hematologic, and hepatic toxicities, and may result in treatment delays. A study of 626 patients receiving dose-dense doxorubicin and cyclophosphamide followed by paclitaxel, a regimen commonly used in breast cancer, identified the incidence of dose reductions and treatment delays to be 29% and 42%, respectively (Weycker et al., 2012). Treatment delays can increase the risk of disease progression and reduce survival (Weycker et al., 2012). Therefore, when utilizing complex chemotherapy regimens, strategies to mitigate toxicities and high financial costs are necessary to improve patient care.

The role of the oncology pharmacist has evolved in recent years. In addition to providing the necessary safety checks associated with dispensing chemotherapy, oncology pharmacists may provide patient and family education, therapeutic drug monitoring, supportive care management, and assist with medication access, among other activities, to optimize patient care (Hematology/Oncology Pharmacy Association, 2019). Recent studies evaluating and quantifying the impact of clinical pharmacists in ambulatory oncology practices report positive results. In 2017, a systematic review by Colombo and colleagues (2017) identified that clinical pharmacist interventions were associated with improved symptom control, supportive care, and patient satisfaction. A single-center study conducted at Duke Cancer Center in 2020 identified 5,091 interventions over 6 months, across 3,967 patient encounters, which were divided among 9 ambulatory oncology pharmacists. Documented interventions were diverse, with the majority including, but not limited to, treatment plan management, symptom management, patient education, and medication administration. Furthermore, numerous provider and nursing survey respondents supported the addition of clinical pharmacists in the clinics. Greater than 80% of respondents strongly agreed or agreed that access to a clinical pharmacist had improved patient care, the pharmacist is helpful in answering drug information questions, and the clinical pharmacist is a valuable member of the team (Meleis et al., 2020).

At the Sidney Kimmel Cancer Center at Jefferson Health in Philadelphia, Pennsylvania, laboratory testing review and treatment assessments for patients undergoing chemotherapy are typically completed by infusion center pharmacists. A pilot program was developed to add an oncology clinical pharmacist to a breast cancer clinic, where the pharmacist worked closely with a breast medical oncologist 2 full days per week. This clinic averaged 12 to 18 visits per day. New patients were seen by the physician, where they received information regarding their diagnosis and treatment plan. In addition to lab and treatment review, the clinical pharmacist provided chemotherapy education, among other interventions, such as medication reconciliations and drug-drug interaction screenings. The pharmacist would follow up with patients after their first cycle of chemotherapy during prescheduled clinic or treatment visits to assess for side effects and provide supportive care recommendations. The pharmacist may continue to see these patients at subsequent clinic visits for side-effect management. Non-pharmacologic, administration-related, or other low-risk interventions were made independently by the pharmacist without prior feedback from the provider. These interventions were documented in the electronic health record (EHR) and were available for provider review. Based on clinical judgment, interventions may also be reviewed with the provider before discussing with the patient. Other health-care providers, such as social workers and nutritionists, were consulted upon referral. Although not all visits involved chemotherapy, the clinical pharmacist reviewed patients for optimization of therapy and evaluation for education. The pharmacist also addressed any drug information questions, including dose modifications based on the presence of toxicities and abnormal laboratory values. The addition of clinical pharmacy services to the ambulatory oncology setting has the potential to improve patient care in this high-risk population. Therefore, this study seeks to

identify the impact of the clinical pharmacist in supportive care management at the breast cancer clinic, add to existing literature discussing the impact of the clinical pharmacists in ambulatory oncology settings, and justify future, permanent ambulatory oncology pharmacist positions within the institution.

METHODS

This single-center retrospective chart review quantified and analyzed a single clinical pharmacist's interventions. Interventions were documented in real-time, using the EHR's iVent tool. Each iVent is linked to a patient's chart and can contain a single or multiple interventions. Patients who were at least 18 years old and presented to the clinic for new chemotherapy for any stage of breast cancer between September 1, 2020, and February 28, 2021, were included in the study. Data from a 6-month report of the clinical pharmacist's iVents were generated and exported to an Excel file. Individual patients were then screened for inclusion in the study. Patients who did not have patient-pharmacist interactions were excluded from the primary analysis. Collected baseline characteristics among patients who met inclusion criteria were age, gender, race, chemotherapy regimen, stage, human epidermal growth factor receptor 2 (HER2) status, hormone receptor (HR) status, and line of therapy. Intervention data were also collected for all patients identified in the 6-month timeframe. This study was approved by the institutional review board at Thomas Jefferson University Hospital.

The primary outcome was to describe the clinical pharmacist's interventions at the first follow-up encounter after chemotherapy initiation (Appendix A). This included identifying the number of days from the first encounter to the first follow-up, encounter type (phone or clinic visit), adverse drug effect (ADE) with corresponding direct supportive care recommendation, and time spent per encounter. "Direct interventions" were defined as clinical pharmacist recommendations that were reviewed with the patient without initially receiving provider feedback. Secondary outcomes included classifying and quantifying total interventions between September 1, 2020, and February 28, 2021, and comparing iVent and intervention details among total and included patients within the 6-month timeframe. Categories to which interventions were classified included coordination of care, education, supportive care pharmacotherapy intervention, chemotherapy dose or medication adjustment, medication reconciliation, non-pharmacotherapy intervention, laboratory or diagnostic review, medication access, drug interaction screening, treatment evaluation, prior authorization or insurance, and referrals. Coordination of care activities included, but were not limited to, reviewing upcoming appointments, adjusting chemotherapy regimen dates, chemotherapy toxicity monitoring, and informing patients when they can initiate treatment. Education includes new chemotherapy education and re-education at future visits. New chemotherapy education includes treatment evaluation and review of the regimen, associated side effects, and side effect management strategies (Appendix B).

Statistical Analysis

Data were analyzed using descriptive statistics. Continuous data were provided as means (standard deviation) or as medians (range). Categorical data were expressed as frequencies and percentages.

RESULTS

In the 6-month timeframe, 575 iVents were screened, of which 207 individual patients were identified and assessed for eligibility. There were 163 patients excluded, and the most common reason for exclusion was not receiving new chemotherapy within the specified timeframe, with 113 patients receiving endocrine therapy or other treatments. Twenty-six patients had non-breast malignancies, 21 did not have patient-pharmacist interactions, and 3 iVents were from inpatient interventions, leaving 44 patients included in the primary analysis (Figure 1). Among the 44 included patients, 29 had a follow-up encounter with the clinical pharmacist (Figure 1). Of the 44 patients, the median age was 58.5 years, 98% were female, 55% were White, and 41% were Black or African American. Sixty-seven percent of patients received chemotherapy with curative intent, and the remaining 33% received chemotherapy for metastatic breast cancer. Among those with metastatic breast cancer, 73% had received at least three lines of therapy. HER2 and HR status are also reported in Table 1.

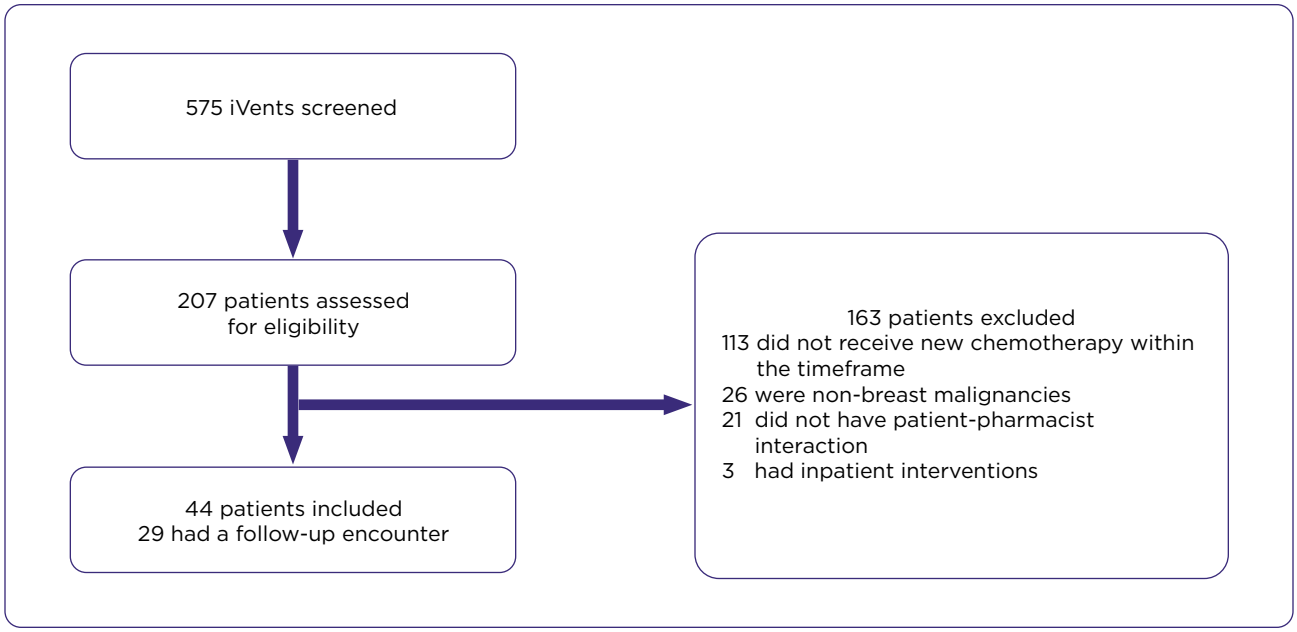

Figure 1. Patient inclusion and exclusion from the primary analysis. There were 575 iVents for 207 individual patients, who were identified and subsequently assessed for eligibility. There were 163 patients excluded, primarily because they did not receive new chemotherapy within the 6-month timeframe. After exclusion, 44 patients remained for collection of baseline characteristics, of whom 29 had a follow-up encounter with the clinical pharmacist after chemotherapy initiation and were assessed for the primary analysis.

Primary Outcome: First Follow-Up Encounter

Of the 29 patients who had a follow-up encounter, the median number of days to first follow-up was 9, of which 93% were made by phone call. There were 24 patients (83%) who reported a total of 58 ADEs, of which 19 ADEs (33%) had a corresponding direct pharmacist intervention (Table 2; Appendix C). Gastrointestinal-related ADEs were the most common (43%), followed by constitutional-related (34%) and pain-related (12%) ADEs. Among gastrointestinal ADEs, nausea, diarrhea, and constipation were the most common. The most frequent direct pharmacist interventions were for gastrointestinal ADEs, including recommendations for the management of nausea, vomiting, diarrhea, and constipation (Figure 2; Appendix D). Management strategies included referrals for intravenous fluids, reeducation on prescription medications, recommendations to add supportive care medications, and recommendations to hold oral chemotherapy for severe ADEs. Severe ADEs that required immediate intervention were documented in the EHR and reported to clinic staff, including the physician, nurse practitioner, and registered nurse for further discussion. Most follow-up encounters were conducted via phone calls, which allowed for quicker follow-up, as many chemotherapy regimens were every 2 or 3 weeks. Overall, among the 24 patients, the presence of a clinical pharmacist resulted in 10.6 hours saved by the provider.

Secondary Outcomes

Between September 1, 2020, and February 28, 2021, the clinical pharmacist made 1,068 interventions spanning 189.6 documented hours. The most common interventions were coordination of care (23.6%), education (12.2%), supportive care pharmacotherapy interventions (11.7%), and chemotherapy dose or medication adjustments (11.3%). Among the 44 patients included in this study, there were 471 interventions across 155 patient-pharmacist encounters and 65.4 documented hours. The most common interventions were coordination of care (22.1%), education (17.2%), supportive care pharmacotherapy interventions (15.1%), and medication reconciliation (8.9%; Table 3). Patients undergoing new chemotherapy consisted of 21%

of all patients yet comprised 44% of the total interventions and 34.5% of the total documented time. The shared three most common interventions among total and included patients were coordination of care, education, and supportive care pharmacotherapy interventions.

DISCUSSION

Numerous studies have investigated the impact of adding clinical pharmacists to various clinics and like our study, have identified positive results (Colombo et al., 2017). At the Sidney Kimmel Cancer Center at Jefferson Health, the pharmacist does not have prescriptive authority. However, 33% of ADEs were still managed directly by the clinical pharmacist. Compared with Meleis and colleagues (2020), who reported using similar iVent documentation, our study identified more interventions and time spent per pharmacist. This may be partially attributed to Jefferson Health's use of iVents for annual performance evaluation, and as a pilot program with a planned retrospective review, there was likely increased effort for complete documentation. Nevertheless, this study demonstrated that the clinical pharmacist worked closely with patients to provide education, develop dosing strategies for prescribed medications, and provide non-pharmacologic interventions for side effect management. The greater proportion of time spent with patients receiving new chemotherapy reflects a need for close follow-up. Increasing the clinical pharmacist's role in providing follow-up care would allow for the division of responsibilities and time saved among clinic staff.

Table 1. Baseline Characteristics (*n* = 44)

Characteristic	*n* (%)
Age, years, median (range)	58.5 (32–83)
Female	43 (98)
Race	
White	24 (55)
Black or African American	18 (41)
Hispanic	1 (2)
Asian	1 (2)
Cancer stage	
I	15 (34)
II	7 (16)
III	6 (14)
IV	15 (34)
Unable to perform	1 (2)
Hormone receptor status	
HER2 receptor positive	16 (36)
ER or PR positive	9 (20)
ER and PR negative	7 (16)
HER2 receptor negative	28 (64)
ER or PR positive	20 (45)
ER and PR negative	8 (18)
Chemotherapy regimens	
Neoadjuvant/adjuvant	31 (67)
Metastatic	15 (33)
Line of therapy for metastatic cancer	
1	2 (13)
2	2 (13)
3+	11 (73)

Note. HER2 = human epidermal growth factor receptor 2; ER = estrogen receptor; PR = progesterone receptor. Additional details on chemotherapy regimens are provided in Appendix A.

Limitations

The limitations of this study were that it reviewed a short 6-month timeframe during the COVID-19 pandemic in the setting of nursing and provider staffing shortages. Additionally, iVents of only one ambulatory oncology clinical pharmacist in a single disease state were reviewed. The major limitations of this study include the reliance on complete iVent documentation. Documentation in the EHR does not include time spent on non-direct patient care activities such as policy and protocol development, cost-saving initiatives, or formulary management. Furthermore, among iVents related to chemotherapy toxicity monitoring, patients may have reported ADEs that were tolerable or resolved with medication; therefore, not all patient-reported ADEs had the opportunity for actionable interventions. These limitations may underestimate the impact of the ambulatory oncology clinical pharmacist. Regardless, this study identified a large number and variety of interventions, and findings were used to successfully justify a full-time position within the Sidney Kimmel Cancer Center at Jefferson Health.

Table 2. Pharmacist Intervention at First Follow-Up Encounter

Category	*n* (%)
Patients	29
Days to first follow-up, median (range)	9 (1–171)
Encounter type	
Phone	27 (93)
Clinic	2 (7)
Patients reporting ADEs	24 (83)
Patient-reported ADEs	58
Direct pharmacist interventions	19
Total documented time, h	10.6

Note. ADE = adverse drug event. Direct interventions are recommendations that were made without initial provider consultation. Specific interventions are provided in Appendix C.

FUTURE DIRECTIONS AND CONCLUSION

To further expand pharmacy services, the next steps would be to add oncology pharmacists to other cancer clinics and to establish collaborative practice agreements (CPA) at our institution. Currently, there is no guideline to assist with developing CPAs in the ambulatory oncology setting. Existing and future studies highlighting the impact of pharmacists on treatment outcomes could be utilized to develop such guidance. For example, the systematic review conducted by Colombo and colleagues in 2017 compiled results of studies evaluating treatment outcomes associated with clinical pharmacist interventions, predominantly among genitourinary, gastrointestinal, breast, and lung cancers. Outcomes included evaluating symptoms of chemotherapy-induced nausea and vomiting (CINV), chemotherapy-induced peripheral neuropathy, patient satisfaction, quality-of-life, adherence to laboratory parameter monitoring, and medication adherence, among others (Colombo et al., 2017). Based on the literature and the present study's findings that the most patient-reported ADEs with corresponding pharmacist interventions were for gastrointestinal-related ADEs, a future prospective study could compare the grade and incidence of CINV, diarrhea, constipation, and patient satisfaction surveys between ambulatory oncology

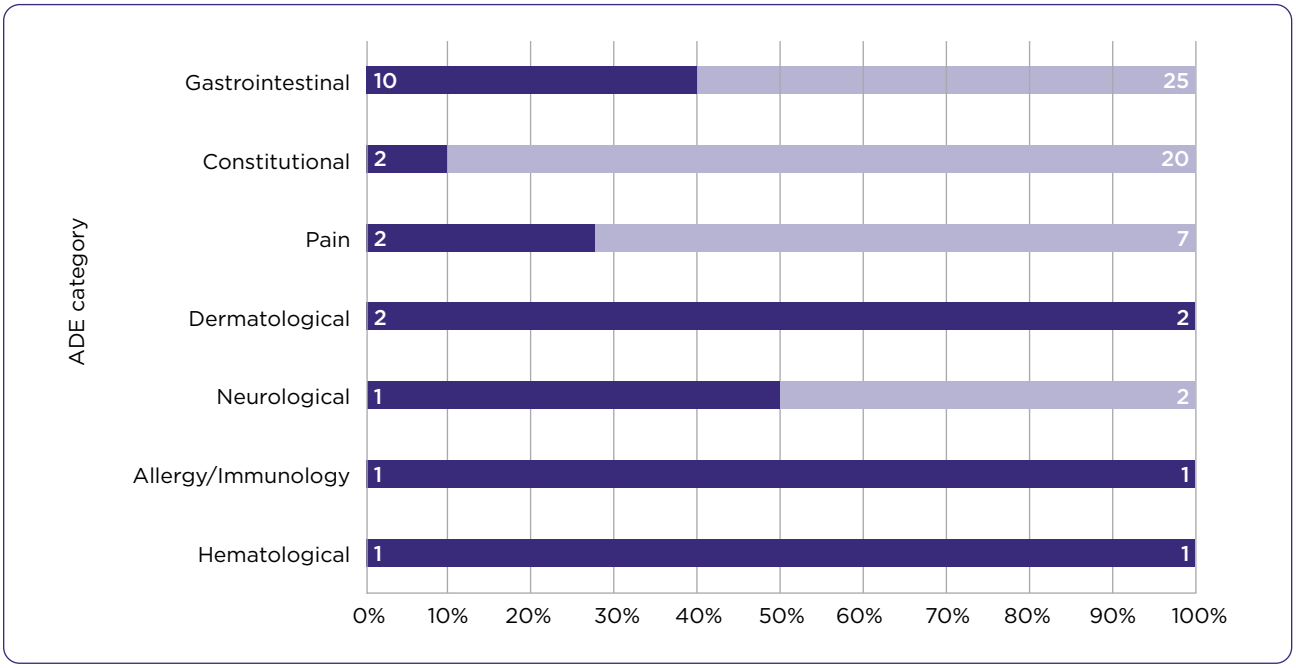

Figure 2. Percentage of patient-reported adverse drug events (ADEs) that had a corresponding direct pharmacist intervention. For example, 40% of gastrointestinal ADEs had a direct pharmacist intervention. Data labels on the right side depict the number of reported ADE per category. Data labels on the left side depict the number of direct pharmacist intervention per category. More details regarding reported ADEs are provided in Appendix D.

Table 3. Intervention Count and Classification Details

Category	Total (*n* = 1,068), *n* (%)	Included (*n* = 471), *n* (%)
Coordination of care	252 (23.6)	104 (22.1)
Education	130 (12.2)	81 (17.2)
Supportive care pharmacotherapy intervention	126 (11.7)	71 (15.1)
Chemo dose or med adjustments	121 (11.3)	7 (1.5)
Medication reconciliation	103 (9.6)	42 (8.9)
Non-pharmacotherapy intervention	70 (6.6)	39 (8.3)
Lab or diagnostic review	63 (5.9)	35 (7.4)
Medication access	52 (4.9)	16 (3.4)
Drug interaction screen	51 (4.8)	32 (6.8)
Treatment evaluation	51 (4.8)	32 (6.8)
Prior authorization or insurance	33 (3.1)	7 (1.5)
Referrals	16 (1.5)	5 (1.1)
Other	5 (0.5)	0 (0.0)
Referrals to social work	5 (0.5)	1 (0.2)
Referrals to infusion center	2 (0.2)	2 (0.3)
Referrals to nutrition	2 (0.2)	1 (0.2)
Referrals to same-day clinic	2 (0.2)	1 (0.2)

Note. Specific intervention activities are provided in Appendix B.

clinics which do and do not have a clinical pharmacist. Since the most frequent intervention was coordination of care, another area to review could be time from first clinic visit to treatment initiation, appointment adherence, and incidence of treatment delays. Additional outcomes to explore in controlled prospective studies include surveying health-care professionals' perceptions of the impact of an ambulatory oncology pharmacist before and after piloting a pharmacist within the ambulatory oncology clinics and performing cost-avoidance analyses, such as assessment for treatment delays, emergency department visits, and hospitalizations. An increased effect may also be seen if examining multiple, as opposed to single, disease states. Results of these studies may assist with developing an evidence-based framework to initiate CPA programs by better identifying the areas in which pharmacists have the most clinically meaningful impact.

Overall, this study reports a successful pilot program and integration of a clinical pharmacist into a breast cancer clinic. We were able to quantify the impact of the clinical pharmacist and identify the pharmacist's role in supportive care management.

Disclosure

Drs. Ganihong and Singh have no conflicts of interest to disclose. Dr. DiMarco has served on an advisory board for Bristol Meyers Squibb.

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Appendix A. Chemotherapy Regimens (*n* = 46)

Regimen	*n* (%)
Neoadjuvant/adjuvant therapy	
ddAC-T	10 (22)
TCHP	8 (17)
Ado-trastuzumab emtansine	4 (9)
Trastuzumab/paclitaxel	3 (7)
Cyclophosphamide/docetaxel	2 (4)
Neratinib	2 (4)
Carboplatin/paclitaxel	1 (2)
Weekly paclitaxel	1 (2)
Total	31 (67)
Metastatic disease	
Capecitabine	5 (11)
Abemaciclib	3 (7)
Capecitabine/trastuzumab/tucatinib	1 (2)
Carboplatin/gemcitabine/pembrolizumab	1 (2)
Eribulin	1 (2)
Paclitaxel/atezolizumab	1 (2)
Palbociclib	1 (2)
Ribociclib	1 (2)
Sacituzumab govitecan	1 (2)
Total	15 (33)

Note. ddAC-T = dose-dense doxorubicin and cyclophosphamide, and paclitaxel; TCHP = paclitaxel, carboplatin, trastuzumab, and pertuzumab

Appendix B. Pharmacist Intervention Activity Details

Coordination of Care

- Review upcoming appointments
- Monitor chemotherapy toxicity without intervention
- Adjust treatment plan dates
- Inform patient of insurance approval of chemotherapy and when to start treatment

Medication Access

- Message billing
- Send prescriptions to pharmacy (refill requests)
- Assist with charity care application
- Coordinate patient assistance programs

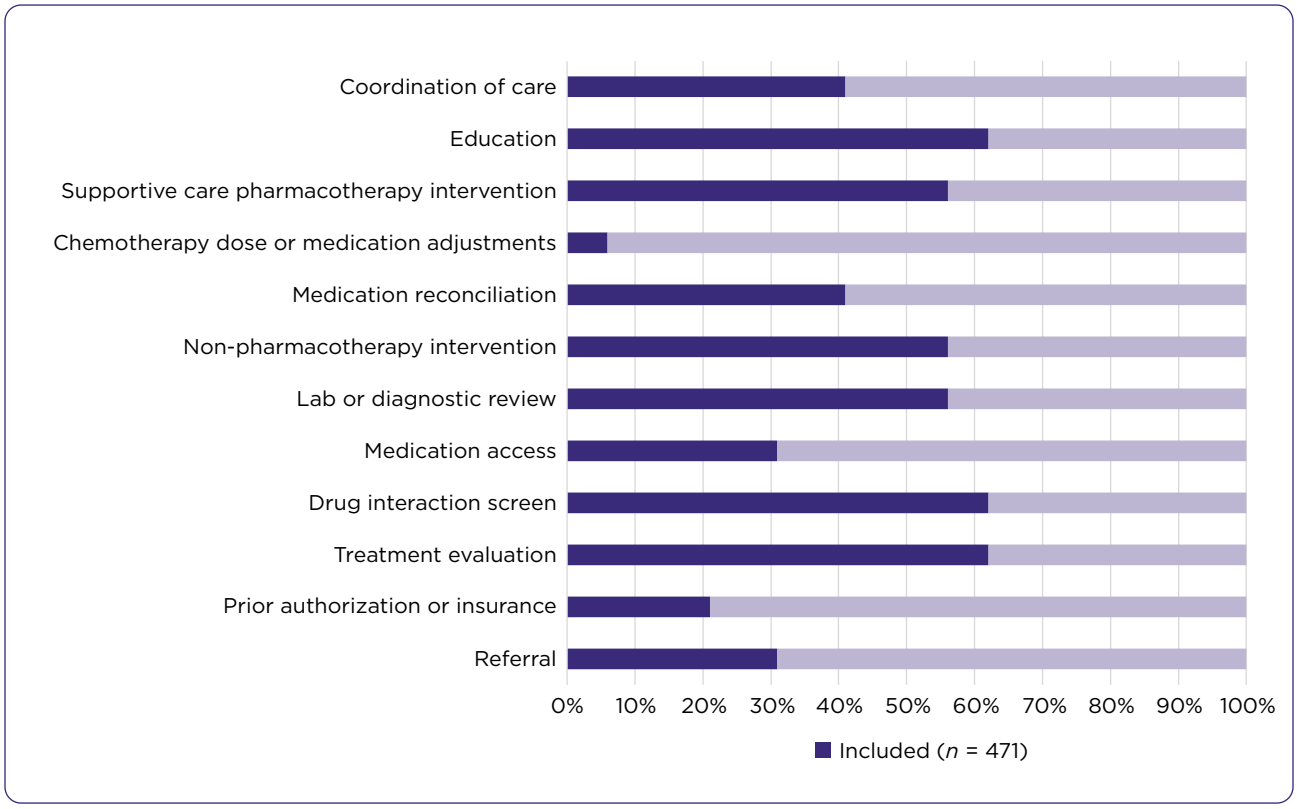
Treatment Evaluation

- Review patient demographics (height, weight, body mass index, body surface area)
- Review required renal adjustments
- Review required hepatic adjustments
- Review emetogenic risk
- Review for any additional necessary monitoring
- Review supportive care management
- Review appropriate pre-medications ordered

Appendix C. First Follow-Up Patient-Reported ADEs and Direct Pharmacist Interventions

ADE category	Patient-reported ADEs (*n* = 58), *n*	Direct intervention (*n* = 19), *n*
Gastrointestinal	25	10
Nausea	11	5
Diarrhea	6	2
Constipation	4	1
Vomiting	3	2
Dysgeusia	1	0
Constitutional	20	2
Fatigue	7	0
Loss of appetite	4	0
Dizziness	2	1
Fever	2	0
Insomnia	2	0
Dehydration	1	1
Flushing	1	0
Night sweats	1	0
Pain	7	2
Bone pain	3	0
Headache	2	2
Chest pain	1	0
Joint pain	1	0
Dermatological	2	2
Dry skin	1	1
Hand-foot syndrome	1	1
Neurological	2	1
Neuropathy	1	1
Gait disturbance	1	0
Allergy/Immunology	1	1
Hypersensitivity	1	1
Hematological	1	1
Neutropenia	1	1

Note. ADE = adverse drug event. Numerical values were totaled for each category of ADE.



Appendix D. Percentage of total interventions that were among patients who met inclusion criteria. For example, approximately 40% of coordination of care interventions occurred in patients receiving new chemotherapy for breast cancer during a pharmacist-patient counter. Less than 10% of chemotherapy dose or medication adjustments occurred among included patients.