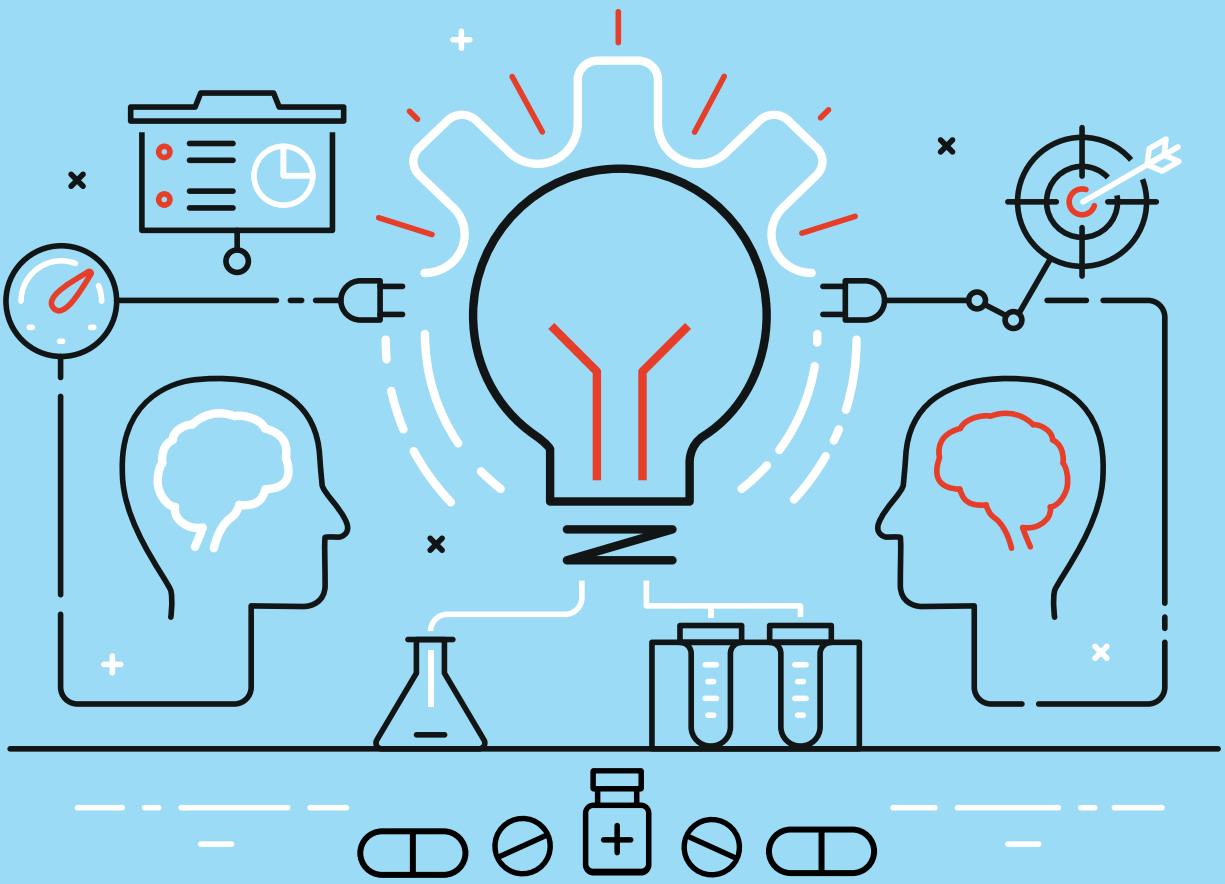
A Pharmacist Collaborative Practice Agreement Improves Oral Oncolytic Workflow and Reduces Treatment Delays



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Rapid development and utilization of oral oncolytics over the past several decades has led to a paradigm shift in the management of patients with cancer. The substantial challenges associated with this shift in care have prompted cancer programs and practices to enlist the assistance of clinical pharmacists to manage treatment and supportive care for patients receiving oral therapies. Through clinical integration, pharmacists can improve medication access, provide chemotherapy order review and medication reconciliation, identify significant drug interactions, monitor patient adherence and side effects, provide patient education, and enhance onsite outpatient pharmacy revenue, among others.[1] Another advantage for pharmacist integration in oncology clinics is the opportunity to dispense prescriptions at provider appointments. This in-office dispensing service is typically provided by a medically integrated pharmacy, defined as "a dispensing pharmacy within an oncology center of excellence that promotes a patient-centered, multidisciplinary team approach."[2] A medically integrated pharmacy is "an outcome-based collaborative and comprehensive model that involves oncology healthcare professionals and other stakeholders who focus on the continuity of coordinated quality care and therapies for cancer patients."[2]

The National Community Oncology Dispensing Association, Inc. (NCODA) is among the major associations advocating for the value of this model. Patient satisfaction surveys collected through NCODA from more than 350 practice sites revealed that patients favored obtaining their oral oncolytics from their physician's offices given the convenience, timeliness, care coordination, and satisfaction with staff interaction.[3] Not only can medically integrated pharmacies provide closer and timely management of patient therapies, but they can also offer the advantage of more cost-effective care. A study conducted at St. Luke's Cancer Institute over a period of six months revealed an annual estimated net cost avoidance of $1,730,416 through in-office dispensing as compared to $119,794 for prescriptions filled through a mail order pharmacy.[4]

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St. Luke's Cancer Institute, formerly known as Mountain States Tumor Institute, established its medically integrated pharmacy in 2010 to manage patients on oral oncolytics. This service was initiated with the dispensing of only two oral oncolytics to patients being managed by a select number of oncology providers. The significant impact of this service on patient care led to the

quick expansion of the program to dispense and manage multiple medications prescribed by all St. Luke's medical oncology providers. Oral oncolytics were originally prescribed using a paper order form that was faxed to the medically integrated pharmacy; however, this process was automated in 2016 with the sitewide transition of St. Luke's Health System to the Epic electronic medical record (EHR). Providers now enter oncology treatment plans in the EHR and then communicate with the medically integrated pharmacy by sending the plans to an assigned oral oncolytic message pool, seamlessly integrating pharmacists into the care of all corresponding patients.

Our Medically integrated Pharmacy At-a-Glance

St. Luke's Cancer Institute's oral oncolytic medically integrated pharmacy is staffed by several pharmacists and technicians who manage the care of more than 500 patients. Pharmacist services are primarily telephone based, as our five clinics serve patients from southwest Idaho, eastern Oregon, and northern Nevada. The filling process for oral oncolytic prescriptions was refined over several years since the establishment of the medically integrated pharmacy. Once the treatment plan is received by the medically integrated pharmacy, technicians initiate a tracking sheet (Word document) for each patient in their individual folder. The patient tracking sheet details the patient's medication dosing and the start date for each cycle to assist in following their treatment. Technicians will also run a drug interaction report with the patient's current medication list, which is saved in the patient's folder. After these steps are completed, pharmacists review the oral oncolytic prescription.

Our review process follows these steps. Patient charts are reviewed for diagnosis and medication indication, followed by a review of the prescription for appropriate dosing based on treatment guidelines and patient specific factor such as renal and hepatic function. The patient's drug interaction report is reviewed to note medications with possible interactions that may need to be addressed with the patient or provider. The patient is then contacted via telephone to introduce the oral oncolytic medically integrated pharmacy and discuss the filling process for a specialty medication, including prior authorization through insurance and possible co-pay assistance. Any outstanding questions regarding medications or appointments for baseline exams are addressed with the patient and the provider, when necessary, to complete the prescription review.

A test claim is then run to determine if the patient's insurance requires the completion of a prior authorization. Originally, prior authorizations were completed by the nursing-managed triage department, but in the past year, the oral oncolytic medically integrated pharmacy assumed responsibility of this process. Pharmacists use the EHR to answer clinical questions related to prior authorization and provider notes are attached for reference. If a prior authorization is denied, pharmacists send the paperwork to the provider to complete for appealing the decision. Once the prescription is approved through the insurance, the claim is run again to determine the patient's co-pay.

If a patient's co-pay is deemed unaffordable, pharmacists contact St. Luke's Cancer Institute's patient financial advocates. These advocates work with patients to find co-pay assistance or patient assistance programs, depending on their financial situation. Once the lowest co-pay for the medication is identified, the prescription is filled by the St. Luke's Boise retail pharmacy, which is associated with St. Luke's Cancer Institute. After the prescription is filled, our medically integrated pharmacy contacts the patient to provide counseling and arrange pickup. When possible, our pharmacists provide this counseling in person. The pharmacist uses the documented start date for the patient's oral oncolytic to schedule weekly follow-up calls through the first cycle—unless the patient has a scheduled appointment with their provider. After this appointment, pharmacists review all provider notes for patient updates and possible changes in therapy.

For subsequent cycles, pharmacists contact patients when they have just over a week of medication on hand to begin the refill process and coordinate delivery or pickup. This conversation with the patient includes review of side effects, adherence, and changes in their medication list. EHR reminders send notifications to the St. Luke's Boise retail pharmacy to fill oral oncolytic prescriptions. A reminder message within the EHR is also created and sent to the medically integrated pharmacy when a new prescription is received. Along with treatment details, these EHR reminders are used by pharmacists and technicians to track and complete tasks related to patient care.

Pharmacists also assist patients who are required by their insurers to use mail order pharmacies or patients enrolled in patient assistance programs. Our oral oncolytic medically integrated pharmacy continues to follow these patients until they have been contacted by the mail order pharmacy or free drug program and have received their medication. After receiving medication counseling, these patients are discharged from the medically integrated pharmacy and followed up by their provider's primary nurse. The only exception to this process is mail order patients treated at the Boise St. Luke's Cancer Institute clinic; these patients are followed by a nurse who works with the medically integrated pharmacy.

Laying the Foundation for Change

Transitioning to electronic entry of oral oncolytic prescriptions in the EHR brought new challenges to the order entry process for providers—who often consulted pharmacists for entry of treatment plans or to make changes to prescriptions. Any time a change in dose, quantity, renewal of refills, or a monthly prescription for Celgene products was needed, the new prescription would be sent back to the provider for signature through the Send Plan function in the EHR. Depending on when the signature request was sent and provider workload, it could take a few hours to several days for prescriptions to be signed. Pharmacists would spend time each day, occasionally multiple times per day, reviewing patient charts for signed prescriptions as providers would not always send notifications when this action was completed. If prescriptions were not signed within a few days of the request

for signature, additional messages are sent to the provider. This process significantly impacted the workflow of the medically integrated pharmacy, causing interruptions in the prescription review or refill processes and, sometimes, even delays in treatment.

To improve the workflow in the medically integrated pharmacy and assist busy providers with patient care, St. Luke's Cancer Institute's pharmacy management team discussed opportunities to expand pharmacist responsibilities, including the implementation of a collaborative practice agreement (CPA). The concept of a CPA dates back many decades to when the American College of Clinical Pharmacy (ACCP) issued a position statement regarding collaborative medication management by pharmacists.[5] In turn, the American Pharmacists Association (APhA) issued consortium recommendations to define CPAs and advanced pharmacist practice. Collaborative practice agreements are documents intended to "create formal relationships between pharmacists and physicians or other providers. CPAs define certain patient care functions that a pharmacist can autonomously provide under specified situations and conditions."[6] Several examples of successful CPAs are currently in practice across the nation. For several years, St. Luke's Cancer Institute pharmacists have been involved in prescribing and managing antiemetics for oncology patients through a CPA. Pharmacists use patient history to assist in selecting the appropriate antiemetic at treatment initiation and communicate with patients through their treatment to further tailor the antiemetic therapy. Based on the success of the antiemetic CPA and the good rapport between providers and pharmacists, St. Luke's Cancer Institute decided to pursue implementation of an oral oncolytic CPA in the medically integrated pharmacy.

Developing the CPA

A pharmacy resident project was designed to assist our medically integrated pharmacy create, implement, and evaluate an oral oncolytic CPA. A literature search revealed that although CPAs are being used in several settings, the practice was not commonplace in oncology pharmacy, especially to the extent at which we were aiming. In other words, creation of an oral oncolytic CPA would be a novel approach to pharmacist assistance with oncology medications.

Based on observations in the medically integrated pharmacy, we compiled a list of clinical activities that oral oncolytic pharmacists would be responsible for under the CPA. Clinical activities included the pharmacist intervention requests sent most often to providers. The most common request to providers was for signature on refill renewals for continuation of therapy, including Celgene products that require a new prescription with each cycle. Dose adjustments based on renal and hepatic function at initiation of and during therapy were included as these labs are reviewed by pharmacists prior to each fill. And because pharmacists are more familiar with available strengths, we included under the CPA the ability for pharmacists to round medications to the nearest tablet size for ease of patient administration and possible cost savings. Allowing pharmacists to renew prescriptions based on provider notes indicating continuation of therapy would have a large impact on workflow, so that was included under the CPA. Dose adjustments for toxicities based on guidelines, the pharmacist's clinical judgment, and provider notes were also included in the clinical activities. Note that a staff message is still sent to providers to confirm dose adjustments for toxicities that are reported to pharmacists or not clearly addressed in provider notes. Another intervention that pharmacists occasionally see is adjustments to the appropriate dose in medications where dosing varies based on indication, which must be addressed before completion of the initial review and can result in treatment delays. Because pharmacists monitor the patients closely, the ability to order lab tests and exams that are recommended for baseline and continued monitoring during treatment was a valuable addition. Inclusion of these clinical activities in the CPA responsibilities would decrease workflow interruptions and allow pharmacists to practice at the top of their license. Table 1, page 36, lists the clinical activities we proposed under the draft CPA.

Improvements in pharmacist workflow at St. Luke's Cancer Institute due to significantly reduced turnaround times of prescriptions has allowed the medically integrated pharmacy to keep up with a rapidly growing patient population.

The draft CPA and the idea of a pilot project involving a small subset of providers was presented to the oncology pharmacy and therapeutics (P&T) committee for provider approval. The pilot project would allow us to evaluate improvements in medically integrated pharmacy workflow, possible patient cost savings, and provider satisfaction prior to CPA implementation in all clinics. Following P&T committee approval of the oral oncolytic CPA and pilot project, 4 providers were approached to request their participation in the pilot as a subset of the 15 St. Luke's Cancer Institute's providers. The pilot providers, or pilot group, were selected based on oral oncolytic workload and their physical proximity to the medically integrated pharmacy to enhance communication. The other 11 providers were considered to be the control group.

Pilot group providers received education on the clinical activities that pharmacists would be able to perform under the CPA. These providers were also notified that they would receive a weekly email detailing the interventions completed for their patients. Education was also provided to the pharmacists in the medically integrated pharmacy on the clinical activities that could be performed with the oral oncolytic CPA, and how to address interventions for patients depending on whether their provider was in the pilot or control group.

Table 1. Clinical Activities Included in Our Draft Collaborative Practice Agreement

Signature on refill renewals for continuation of therapy.
Dose adjustments based on renal and hepatic function at initiation of and during therapy.
The ability to round medications to the nearest tablet size for ease of patient administration and possible cost savings.
Renewal of prescriptions based on provider notes indicating continuation of therapy.
Dose adjustments for toxicities based on guidelines, the pharmacist's clinical judgment, and provider notes.
Adjustments to the appropriate dose in medications where dosing varies based on indication.
The ability to order lab tests and exams that are recommended for baseline and continued monitoring during treatment.

The pilot was designed to allow comparison of interventions made by pharmacists through the CPA in the pilot group with suggested interventions sent to the control group. Data collection for the pilot group included type of intervention required, turnaround time of prescriptions, patient cost savings, and provider satisfaction. Data collection in the control group was designated as interventions recommended, turnaround time of prescriptions, and delays in new orders. The pilot planned for two months of data collection before results would be presented to the oncology P&T committee.

In the pilot group, once the need for an intervention was identified, pharmacists would make prescription adjustments and then sign on behalf of the provider, with reference to the CPA in the comments section of the signature screen in the EHR. Pharmacists would then proceed with the normal workflow in addition to documenting the intervention in a shared pilot group spreadsheet. The pilot group spreadsheet was then reviewed by the data collector to assign time values based on the type of intervention. Interventions were assigned a value of the time it would take the pharmacist to complete the task to avoid any additional impact on their workflow. Simple tasks such as refill renewals or dose adjustments were given a value of 5 minutes to identify the intervention and enter a new prescription. Interventions that were given a value of 10 minutes included those that required a more detailed review or Celgene renewals due to the added documentation with the risk evaluation and mitigation strategy (REMS) program requirements. A value of 15 minutes was assigned to prescriptions where multiple interventions were completed.

In the control group, the normal medically integrated pharmacy process was followed once interventions were identified. Pharmacists would update the prescription in the treatment plan and then send a staff message to the provider informing them of the suggested intervention, upcoming start date, and requesting a signature if they would like to proceed. These messages were also sent to the medically integrated pharmacy message pool to provide visibility of the response to all team members. The data collector was included on these staff messages during the pilot to update the control group Excel spreadsheet with the time the pharmacy message was sent to the provider; the time the prescription was signed and received was also recorded. These values were used to show the amount of time it took for a prescription requiring an intervention and provider signature to be ready for a pharmacist to review.

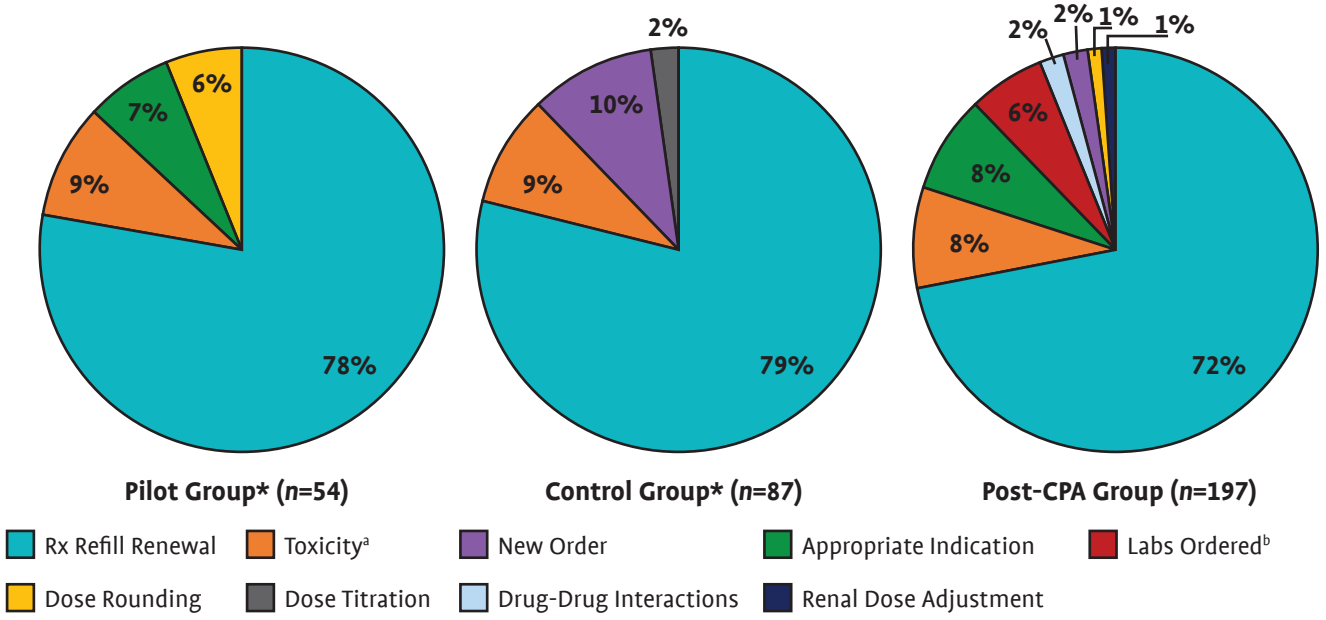
Study Results

At the end of two months of data collection, preliminary data was finalized for presentation to the oncology P&T committee. A survey was also conducted in the pilot group to show data on provider satisfaction with the oral oncolytic CPA. Based on these data, the oral oncolytic CPA was approved for sitewide implementation in all St. Luke's Cancer Institute clinics. Due to the timing of the P&T meeting, three months of pilot data collection was completed, which allowed time to educate to St. Luke's Cancer Institute providers before the oral oncolytic CPA was implemented systemwide. We decided to continue data collection for an additional three months following systemwide implementation of the CPA to further evaluate the impact on workflows. To distinguish between the data collected before and after CPA implementation, results were discussed as part of the pilot phase or the post-CPA phase.

Pilot Results

In the pilot phase, data was collected on 141 total interventions, with 54 in the pilot group and 87 in the control group. Interventions recorded in the pilot group included prescription refills, adjustment for toxicity, adjustment for appropriate indication, and dose rounding. The control group interventions included refill renewals, adjustment for toxicity, new orders, and dose titration. Breakdown of these interventions can be seen in Figure 1, page 37. The total turnaround time for the 54 pilot group interventions was 365 minutes, with the average time spent on each intervention at 7 minutes. In the 87 control group interventions, the total turnaround time was 399,999 minutes with an average of 3,311 minutes per intervention. Three outliers were identified in the control group for prescriptions unsigned after an extended length of time and were removed from the data prior to statistical analysis. The oral oncolytic CPA was shown to have a statistically significant ($p < 0.0001$) impact on decreasing prescription turnaround times, as seen in Table 2, page 38. Dose rounding that resulted in patient cost savings was reported on two prescriptions. Suggested wholesale prices for capecitabine and temozolomide were used to determine cost savings. Dose rounding for capecitabine and temozolomide resulted in savings of $9,858.24 per year ($547.68 per cycle) and $3,281.85 per year ($252.45 per cycle), respectively.

Figure 1. Intervention Results of Pilot, Control, and Post-CPA Groups



NOTES: *Pilot phase (*n* = 141): pilot group (*n* = 54) and control group (*n* = 87). CPA = collaborative practice agreement. [a]Hand-foot syndrome (*n* = 8), diarrhea (*n* = 6), neutropenia (*n* = 5), nausea (*n* = 4), and neuropathy (*n* = 3) were the most commonly observed reasons for dose reductions due to toxicity in all groups. [b]Complete blood count (CBC, *n* = 4), complete metabolic panel (CMP, *n* = 5), phosphorus (*n* = 3), uric acid (*n* = 3), and pregnancy test (*n* = 4) were ordered in the post-CPA group.

A three-statement survey using a Likert scale measured provider satisfaction with the interventions and support of systemwide CPA implementation. Three of the pilot group providers strongly agreed and one provider agreed with all the statements, with all verbally expressing support of the oral oncolytic CPA after the survey.[7]

Post-CPA Results

In the weeks prior to systemwide implementation of the oral oncolytic CPA, education was provided to all 15 providers. Pharmacists in the medically integrated pharmacy were also given further education on order entry for labs and exams, and instructed on plans for data collection in the post-CPA phase. Pharmacists were instructed to use the same method for completing prescription interventions per the CPA as in the pilot group. Reference to the CPA was still included in the comments section of the EHR when signing prescriptions. For data collection, pharmacists sent a reminder with a brief description of the intervention completed, and the data collector filled in the Excel spreadsheet for the post-CPA data. Time values for interventions made in the pilot group were also applied to data from the post-CPA group.

Over three months, 197 interventions were made in the post-CPA group. The interventions completed were similar in breakdown to the pilot and control groups for the pilot phase, as seen in Figure 1, above.[7] Total turnaround time for the post-CPA group was 1,190 minutes, averaging 6 minutes per intervention. Comparison of the post-CPA group to the control group also showed statistical significance for decreased turnaround times on prescriptions when interventions are signed on behalf of the provider per the CPA (Table 2, page 38). Provider feedback was requested through an email sent to each of the providers detailing the interventions made with the oral oncolytic CPA in the post-CPA phase. Only one provider responded with a question regarding future notification of interventions.[7] An official survey was not completed in the post-implementation phase; however, provider approval of the oral oncolytic CPA was heard by word of mouth throughout the clinic locations.

A noted limitation of data collection in both phases is that all data may not be represented. Due to delays in pharmacist education (based on their schedule), some of the possible interventions in the pilot and control groups may have been missed. Some instances of forgotten notifications to the data collector were also observed in the pilot, control, and post-CPA groups. Despite this limitation, the data still showed a significant difference in the turnaround time of prescriptions.

Table 2. Turnaround Times from Pilot, Control, and Post-CPA Groups

Pilot Group (*n*=54)	Control Group (*n*=87)	Post-CPA Group (*n*=197)
Total Turnaround Time: 365 minutes	Total Turnaround Time: 399,999 minutes	Total Turnaround Time: 1,190 minutes
Turnaround Time Range: 5–15 minutes (Average 7 minutes)	Turnaround Time Range: 10 – 20,565 minutes (Average 3,311 minutes) Outliers: 30,075, 41,549, & 50,245 minutes	Turnaround Time Range: 5 – 15 minutes (Average 6 minutes)
Mean Turnaround Time* (p<0.0001)		*Excluding outliers

CPA = collaborative practice agreement.

There were 141 interventions completed in the pilot phase. Comparison of turnaround times between the pilot and control groups showed a statistically significant decrease in turnaround times in the pilot group with interventions made through the CPA. The turnaround times for prescriptions in the post-CPA group were also decreased by a statistically significant margin when compared to the control group.

Importance of a Team Approach in Implementing a CPA

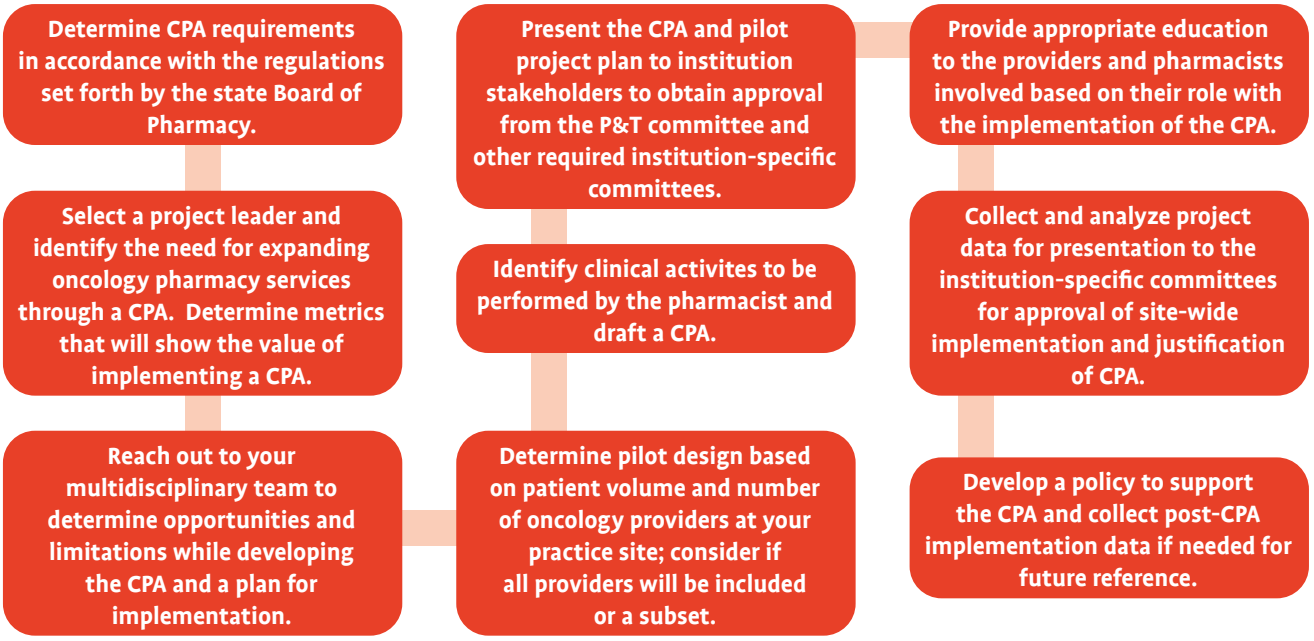
As healthcare continues to evolve and specialties continue to play an integral role in patient care, cancer programs and practices are embracing a multidisciplinary team-based approach. Leveraging the expertise of every member of the healthcare team not only assists providers, but also results in more comprehensive care for patients. With continued medical advances and expansion of medication options in oncology treatment, pharmacists are recognized as valuable resources within the clinic for drug information and management. Cancer programs interested in implementing a CPA can follow the key steps outlined in Figure 2, right.

Pharmacists should consult their state Board of Pharmacy for regulations in place on pharmacist practice with CPAs. It is important to identify a project leader and discuss what the team hopes to achieve by implementing a CPA. Building good rapport within the multidisciplinary team is key to effective communication in discussions about expanding pharmacist services in the cancer program. Open discussions with the oncology team can help identify areas of medication management where providers require additional assistance, or that pharmacists know would increase support to both patients and providers. Whereas all cancer programs and practices may not have a medically integrated pharmacy associated with their clinic, this should not be considered a barrier to implementing a similar oral oncolytic CPA. Pharmacists can still assist with reviewing and adjusting prescriptions based on the clinical activities agreed on by the multidisciplinary team before prescriptions are sent to specialty pharmacies to be filled.

Once you have an outline of your CPA goals, create a draft following your institution's policies that will be shared with the oncology team. Determining the ideal design of a pilot project for your cancer program is another important step to allow for the appropriate evaluation of CPA outcomes. The drafted CPA and plans for a pilot project should be shared with various stakeholders at your institution for approval. It is important to note if there will be any changes in cost to the institution with implementation of the CPA. Following approval of the CPA and pilot, all team members involved will need education. Education should be timely to ensure your data collection is not impacted. Preliminary evaluation of data as you are collecting can assist in identifying limitations and determining what steps can be taken to assist in improving data collection, especially if related to education. At the conclusion of data collection, be sure to report the results to the same stakeholders that approved the pilot to show the impact the CPA had on your endpoints. This will also provide an opportune time to initiate implementation of your CPA with all providers if a subset was used during the pilot. The decision on whether further data collection after the CPA is implemented will be up to the discretion of your institution.

Pharmacist assistance with oral oncolytic prescriptions can have a large impact in any oncology clinic. Improvements in pharmacist workflow at St. Luke's Cancer Institute due to significantly reduced turnaround times of prescriptions has allowed the medically integrated pharmacy to keep up with a rapidly growing patient population. Provider workflow improvements were also noted as they are now able to focus on other patient care responsibilities and entrust the management of the finer details of medications to the pharmacists. Moreover, CPAs allow pharmacists to practice at the top of their license, providing greater job satisfaction. OI

Figure 2. Guide to Implementing a CPA.



Notes: CPA = collaborative practice agreement; P&T = pharmacy and therapeutics.

Stepwise guide based on St. Luke's Cancer Institute's experience to assist with creation, implementation, and evaluation of a CPA.

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