

Quality Improvement for Oral Oncolytics

Amy Hartman

Oregon Health & Science University

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The Clinical Problem

Cancer is a major public health problem worldwide and is currently the second leading cause of death in the United States. Cancer incidence has risen and is expected to continue to increase especially related to the aging population in the United States, with 60% of cancer patients being 65 years or older (Liewer & Huddleston, 2015; Weingart, 2008). Between 2010 and 2020, it is expected that the number of new cancer cases will increase about 24% in men and 21% in women (Weir, Thompson, Soman, Moller, & Leadbetter, 2015). With this increased number in patients, it is essential for oncology practices to be prepared for the influx of patients (ASCO, 2016). This is true for all aspects of an oncology clinic, but perhaps especially so for the management of patients receiving oral oncolytics.

For obvious reasons, oncologic care has worked to move away from the toxic inpatient intravenous chemotherapy treatment strategies and toward the development of more convenient oral therapies that patients self-manage at home. Mercaptopurine and methotrexate were the first oral chemotherapy agents approved in 1953 (Mancini, & Wilson, 2012). Since that time, the use and development of new oral agents has increased in cancer care and has resulted in a shift in the way cancer care is provided. In 2012, up to 35% of the new oncology drugs were oral agents (Mancini, & Wilson, 2012). As of 2013, more than 50 oral anticancer drugs had obtained Federal Drug Administration (FDA) approval and were available on the market (Geynisman & Wickersham, 2013). Due to the recent increase in the quantity of FDA approved oral therapy regimens for the

treatment of cancer, drug choice has transitioned from infused or injectable medications to oral agents. Albeit more convenient for many patients, the preparation of oral chemotherapy regimens is complex and permits for a variety of opportunities for error, largely in part because more responsibility has been shifted to the patient. Therefore, evaluating appropriateness of medication, ordering and routing the prescription, verification of insurance benefits, monitoring and managing side effects, drug-drug interactions, patient education and adherence are fundamental components to oral chemotherapy management and will need to be addressed to meet growing population and drug options (Zerillo et al., 2015). Although all of these barriers exist, the focus of this project was to evaluate the systemic barriers that providers and staff have to an optimal oral chemotherapy process.

Oncology clinics are faced with how to respond to a rapidly changing oral chemotherapy landscape. Oral administration of anti-cancer drugs has become part of many treatment protocols. Thus, patients are now confronted with the option of treatment with an oral chemotherapy agent that provides them increased freedom but potential for increased side effects if not managed properly. Appropriate management of these medications improves adherence to medications and improved safety (Weingart et al., 2008). Unlike most other drugs, anti-cancer drugs generally have a narrow therapeutic window, and the opportunity for significant adverse events is greater than in other therapeutic areas (Zerillo et al., 2015). Medication safety practices have greater significance and need to be more stringent when anti-cancer drugs are provided. Improper under or over adherence to oral chemotherapy medications may cause an increase in adverse effects, healthcare costs, and poor clinical outcomes (Krzyzanowska

& Powis, 2015; Spoelstra, et al., 2013). The complexity of treatment regimens designed to achieve maximal anti-cancer effect balanced against acceptable toxicity leaves limited margin for error. Therefore, to ensure improved safety, development and reinforcement of an informed standard process for oral therapy administration is needed.

Previously, nurses spent more time chair side administering intravenous chemotherapy treatments; however, due to evolution of new therapies, roles have shifted. Oncology nurses now must spend time educating patients and caregivers on the use of these therapies, often over the telephone. The complexity of these therapies and a reduced level of provider-nurse contact have increased the need for consistent education (Mancini & Wilson, 2013; Moody & Jackowski, 2010). Cost limitations for patients on oral oncolytics are a major barrier to obtaining the medication, which is further complicated by insurance companies dictating which specialty pharmacy must be used. The addition of this specialty pharmacy to the healthcare team outside of the patients' primary oncologist may result in patient confusion and creates the need for coordinated care (Weingart et al., 2008).

Purpose

The purpose of this project was to understand the current barriers to standardization of oral oncolytics within a local community hematology oncology clinic and to work with staff and patients to create a protocol that meets the needs of all stakeholders. Standardization is a key component for patient adherence, which is an important aspect to oral chemotherapy safety. This doctor of nursing practice (DNP) quality improvement project focused on one clinic with the potential for improved standardization across the local health system. A standardized process for oral

chemotherapy management will minimize medication errors, improve the adherence, diminish adverse side effects, and improve patient safety.

Literature Review

Methods

The focus of this literature review included safe administration and management of oral chemotherapy. The current trends in cancer treatment, highlighting the management strategies, potential complications and cost effectiveness, were examined. A comprehensive search of literature was performed using MEDLINE and CINHALL databases to identify relevant articles. No date limits were specified. The terms used in the search were oral chemotherapy, adherence, management, guidelines and safety. The initial search identified 102 studies, of which a total of 14 met the criteria and were included in the review. Articles were considered relevant if safety, standards, management, adherence, or guidelines pertaining to oral chemotherapy were mentioned.

Since the initiation of the first oral chemotherapies in the 1950s, the market has been flooded with the rapid development of new oral agents allowing for more convenient treatment options. However, the current literature search demonstrated that management systems are inadequate in ensuring safe administration and patient adherence to oral therapy (Zerillo et al., 2015). System adherence factors include patient relationships with providers, cost of oral oncolytics, system processes and monitoring (Lombardi, 2014). Despite best efforts, oral chemotherapy is also characterized by lack of standardized processes and limited resources to support patients and providers (Krzyzanowska & Powis, 2015).

Guidelines

The current consensus guidelines for oral chemotherapies were established by the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) and Oncology Nursing Society (ONS), and Quality Oncology Practice Initiative (QOPI). The NCCN multidisciplinary task force was created to address impact of the changes in chemotherapy administration and to bring common misconceptions around oral chemotherapy to light and identify future trends in treatment (Weingart et al., 2008). Per the NCCN Task Force Report (2008), some of the factors affecting safe administration include complex treatment regimens, inefficient clinics and process of care, patients' poor communication with healthcare providers, medication errors, and manner of medication distribution. Therefore, the task force recommended that interventions for preventing medication incidents with oral anti-cancer drugs should directly attempt to address these factors.

In 2013, ASCO/ONS collaborated and published chemotherapy administration, prescription and preparation safety standards exclusively addressing safe administration for oral chemotherapy (Neuss et al., 2013). In one report, it was shown prescribing errors were reduced by 69% when the ASCO/ONS safety standards were used in conjunction with computerized provider order entry (Meisenberg, Wright, & Brady-Copertino, 2014). Given the lack of standardization nationally, this is a promising statistic as it indicates that with the utilization of guidelines and electronic medical records (EMR) improved workflow can be accomplished.

The QOPI has developed oral chemotherapy specific quality measurements that focus on staffing, practice, chemotherapy order standards, chart documentation and patient consents for best practices (QOPI, 2014). This voluntary program is the driving

force for the improvement and standardization of oral chemotherapy management.

Practice standards also provide a benchmark for evaluating the quality of services and patient care.

Literature

Prescribing, dispensing and administration errors related to chemotherapy that result in patient harm are well documented in the literature. Neuss et al (2013) discussed that it is important to consider the barriers to implementation of ASCO/ONS safety standards given the amount of oversight needed to monitor oral chemotherapy. Potential barriers include drug handling (storage and disposal), and sources of medications from specialty pharmacies unfamiliar to the prescribing physician. In addition, the high cost of oral agents may lead to impediments to prescribing oral anti-cancer drugs. Furthermore, the standards may be revised based on the feedback from healthcare providers for best practices and safety. Consequently, quality improvement projects in the oncology clinic are needed in order to determine barriers and to improve safe administration standards.

A study done by Zerillo et al., (2015) using QOPI performance results to understand national measures of oral chemotherapy treatment examined plan documentation, patient education, adherence and toxicity monitoring. They observed that plan of care documentation and patient education scored poorly further indicating large gaps in oral chemotherapy management. Regardless, there are opportunities for improvement for patients taking oral oncolytics.

Moody, & Jackowski (2010) support nursing involvement and indicate that patient education is key to successful treatment with oral chemotherapy. However, they recognized that the oral chemotherapy process required significant nursing time for the

initiation of therapy and patient education. One of the barriers that the local oncology clinic targeted for this project has identified is limited nursing staff to manage both triage phone calls and oral chemotherapy treatments. An increase in number of patients served by the clinic as well as an increase in oral chemotherapy treatments, have generated a concern about the sustainability of the current processes.

As mentioned previously, financial limitations are a significant factor that affect oral chemotherapy adherence. Newer oral chemotherapy agents are more costly averaging \$10,000 per month, and sometimes up to \$30,000 (Ratliff, 2016). Therefore, depending on insurance coverage some patients may pay up to 20-30% out of pocket costs for treatment (Vioral, Leslie, Best, & Somerville, 2014). Because Medicare will not pay for oral medication under both part B and D, some patients may fall into the doughnut hole, causing a gap in coverage where they must pay full price (Moody, & Jackowski, 2010). Thus, these exorbitant costs require a significant investment of time and energy for the financial coordinators to determine coverage with an emphasis on the verification of insurance coverage.

A qualitative research study performed in the United Kingdom aimed to identify the perception of healthcare professionals on available oral chemotherapy services. Furthermore, requirements for the implementation of the aforementioned services in community pharmacies were discussed (Butt & Ream, 2016). This was accomplished by semi-structured, individual face-to-face interviews and then data was coded and analyzed (Butt & Ream, 2016). The interview design of the study was helpful in gaining insight about healthcare professional's levels of training and competency in the community setting. It highlighted the need for safe infrastructures and educational opportunities for

pharmacists in future planning and implementation. The results from this study further support the value of engaging a multidisciplinary team when implementing oral chemotherapy services within the community.

Conduct of the Project

Project setting

The project was implemented in a local urban not-for-profit community oncology clinic, which is representative of growing oncology practices in the country utilizing oral chemotherapy without a well-defined and organized process. The improvement process focused on emerging technology, new knowledge and high-risk areas to evaluate best practices for clinical service to cancer patients. The survey was given to all employees in the clinic who have a role in prescribing, obtaining, or administering oral chemotherapy. In addition, time was spent in direct observation of the processes currently in place to assess existing gaps in care. After the survey was administered, a qualitative study design was used to gain additional insight into the issues and perspectives that might present as barriers to the improvement of the oral chemotherapy process. Then extraction of specific data to understand barriers and themes with the process was completed.

The clinic under evaluation for this project was a QOPI certified cancer center. However, the exact QOPI performance results for the clinic was unknown. In the article by Zerillo et al. (2015), the investigators examined data from 155 oncology practices that were participating in the QOPI quality program. The study provided insights showing high variability with documentation and patient education, further encouraging standardization and practice improvement in these specific areas. (Zerillo et al., 2015).

Clinic statistics obtained for quantitative data analysis included the total number of patients seen, number of patients on oral chemotherapy, oral agents most commonly prescribed, cost and reimbursement of medications, and number of oral chemotherapy referrals. Furthermore, the number of patients who experienced a grade three or four reactions to oral chemotherapy (per the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE v4.0) before and after the implementation of this project was obtained with the intention of using this information as a benchmark to demonstrate a decrease in preventable side effects (NCI, 2010). In conjunction with the survey, newly developed oral chemotherapy orders, and national guidelines, a new process was to be initiated to help standardize the current practice. The survey was handed out after the protocol to evaluate the effectiveness of the intervention and continued barriers.

Anticipated barriers

The staff within this individual clinic was ready for improvement in order to meet the influx and changing needs of the patient population. However, due to the limited number of nurses with specialty training in oral chemotherapy management and lack of clinic resources, the pace in which change can be accomplished has been hindered. While 98% of the nurses are Oncology Certified Nurses, the majority are not well versed in oral oncolytics. Additionally, the limited accessibility of clinic resources available to dedicate to process improvement will hinder the pace at which change can occur. Furthermore, the clinic is expanding at a rate greater than the current system can maintain. Last, the clinic is part of a macro system, where changes must be approved at multiple levels to ensure

they align with the overall goal of the organization. The long and tedious approval chain can slow down progress of a quality improvement project.

Another challenge was the upcoming changes to the workflow process later this year due to the new oral chemotherapy orders that is under development. The EMR is essential to an improved process however, there are functional limitations because of standardization across the health system. Inflexibility of the EMR has forced the staff to create workarounds to make the process meet their needs, which also hinders the standardization.

Anticipated facilitators

An escalation in the use of oral chemotherapy agents has resulted in the need for improved workflow processes to increase patient outcomes. The facilitators to the project were; familiarity of the current clinic workflow, necessity to improve management of oral oncolytics, support from management team and desire to maintain QOPI certification.

Another important facilitator was the involvement of the program pharmacy manager for oncology. The addition of a clinical pharmacist with specialization in oral chemotherapy to the management process will add another layer of safety and complement nursing interventions.

Population and plan

The population of concentration was all oncology staff at the local clinic involved in the management of oral chemotherapy that included: medical doctors, nurse practitioners, nurses, financial coordinators, and pharmacists. They were included if they currently help to manage the oral chemotherapy process and work at the specific eastside clinic location. Approximately 13 providers, four pharmacists, 10 nurses, seven medical

assistants and one financial coordinator were identified as being integral to the oral chemotherapy process. The survey was distributed and follow up was done to encourage participation.

Ideally, the data gleaned from this intervention will translate to other clinics, however, the rationale for restricting the assessment to one clinic was the immediate need for process improvement. In order to ensure participant anonymity in a small survey sample, Providence internal review board (IRB) recommended using educational level rather than title or names for the quantitative data that was collected.

Proposed implementation and outcomes

Once the survey and analysis was completed, it was compared with QOPI/ASCO/ONS guidelines to understand standards that are being met as well as identify potential deficiencies. This information was presented to necessary management and staff and a new protocol was developed along with updated oral chemotherapy order sets. It is anticipated that the new process and oral chemotherapy education will be incorporated into employee education and annual competencies. In the future, the process will be re-evaluated by stakeholders to identify if and in what ways oral chemotherapy practices have improved. The proposed outcome is that recognizing barriers and inefficiencies in the current processes will reveal the potential for improved workflow and medication adherence. The main electronic information system to be utilized for this project is the Epic EMR. Ongoing Epic updates will influence changes made to the process.

A new protocol will be especially helpful in the clinic setting where there are varied perspectives on why there is not a standard process. It will also aid in finding

where the breakdowns are located in the oral chemotherapy order, review, and dispensing process in the clinic to better serve the staff and ultimately the patients. The benefit of this project design is that it is cost effective, and it provides the stakeholders information about human behaviors, emotions and routines of staff members.

Implementation of Project

The quality improvement project consisted of three phases. In the initial phase, preliminary data was collected for the project around the current issues and challenges with oral chemotherapy encountered by key stakeholders. The initial assessment revealed the following gaps in the current practice setting:

1. *Lack of consistent processes*: Healthcare providers do not follow a standard process for oral chemotherapy treatments. For example, nurses may electronically order, call in, or send faxes for the initiation of the medication making it hard to track the orders.
2. *Insufficient follow-up calls*: Due to the lack of staff and time, toxicity management and follow up calls are not done in a timely fashion.
3. *Inefficiencies around refills*: Communications about refills to nursing staff are poor. Providers may communicate the refills in multiple ways such as staff communication, chart notes, emails, faxes, treatment plans, and phone messages. Similarly, there is no standard way to communicate refills to the patients.
4. *Lack of standard educational resources for the patients*: There is not always an educational handout for the specific oral agent. Due to the varying degrees

of nursing knowledge, the patients may get different levels of education about the drug.

5. *Lack of timely updates to the EMR System:* The order sets for the new oral chemotherapies are not available within the electronic medical records systems.
6. *Lack of clinical pharmacist involvement:* The clinical pharmacist is not involved in the current oral chemotherapy process. Clinical pharmacist needs to check the drug-drug, drug-disease and drug-food interactions. They also need to be available for educating patients.
7. *Increasing number of oral chemotherapies:* The rapid growth in number of FDA approved oral chemotherapies makes it hard to keep the staff up to date and to manage the therapies.

In the second phase, the potential gaps that were found in the practice setting were analyzed and addressed. A new protocol (see Figure 1) was developed with guidance from the national guidelines and clinic management team that outlined a standard process once the oral chemotherapy order is initiated. Within this new protocol, follow up phone calls are built into the process and should occur within 5 days after the patient starts the medication. An addition of a second phone triage nurse was approved to help with the influx of oral chemotherapy management. After further discussion providers were educated to only send refill communication via chart notes to the oral chemotherapy bucket to streamline the refill process.

During this time internal review board (IRB) approval was obtained from Oregon Health and Sciences University along with the local Providence review board. There was

a significant delay in attaining approval from the Providence IRB, which modified the original timeline. Constantly evolving changes within the healthcare system also contributed to the difficulty of this project. Furthermore, recent approval of expansion into a new clinic space complicated the development of potential workflows to the oral chemotherapy process as what maybe effective now may not be applicable in the future. Despite many challenges, the project was still able to encapsulate the major issues of the current processes in the clinic.

In the final phase, a presentation regarding standardization with a new protocol, change in workflow processes, and preliminary policy and procedure outline (as show in Figure 1) was given to the staff that would be involved in the new oral chemotherapy process. Following the presentation, the management team distributed a paper survey to staff. A five-point Likert-type scale ranging from 1 (strongly agree) to 5 (strongly disagree), along with one “other” was used for the 14 content items, in Table 1. The survey consisted of 20 questions: six general demographic information, 14 that addressed common barriers in the practice, current understanding of oral chemotherapy dispensing and educational resources. Staff was reminded one week after the presentation to complete the survey.

Results

There were 17 participants in the final sample size, for a response rate of 68%, as shown in Table 2. The overwhelming majority were female (88%) respondents who mostly received a bachelor’s degree or above (82%). 35% of individuals have more than 15 years of oncology experience however, only 13% of the participants had more than 15 years of experience with oral chemotherapy. Most of the respondents (44%) had one to

five years of experience working with oral chemotherapy. These findings highlight the importance of staff education and shows that number of years spent in oncology care does not necessarily correspond to increased knowledge in oral chemotherapy.

65% of respondents thought having standardized educational materials were needed in order to improve patient adherence. Furthermore, a dedicated appointment time to adequately teach the patient about oral chemotherapy medication was identified as an area of opportunity in this survey. About 71% of respondents did not feel that there was a standardized manner to track which patients were receiving oral chemotherapy and the development of a running log would increase the staff's ability to monitor the patients.

Practice related recommendations

With the increasing prevalence of oral cancer agents, organizations need to invest in their prescribing practices and safe handling standards. Respondents in both the national and local surveys indicated that standardized patient education and symptom management resources would help to care for this patient population and increase adherence. In addition, one on one patient and caregiver education is a crucial component to improved patient adherence and decreased fragmentation of care. Standardized educational materials that included the name of medications, management of common side effects and advice on when to contact the office would also be beneficial.

Additionally, practices should develop policy and procedures to assist in multidisciplinary communication and enhance safety. At this clinic, a dedicated interdisciplinary work group for oral chemotherapy management was established to further evaluate these challenges in an organized manner. This new team consists of the medical director of the cancer center, Credena Specialty Pharmacy, clinic pharmacists,

providers, financial coordinators, schedulers, nursing, and clinic management. The panel will work to further develop and implement policies to improve the oral chemotherapy program.

Future changes should focus on the practice of standardized electronic order sets for all oral agents to improve consistency of provider orders and prescription writing. A survey to gain insight on how to better assist with adherence and safety should be given to patients currently taking oral oncolytics. This can be done in order to understand barriers that patients face when they are taking these medications at home.

The ineffectiveness of the current oral adherence processes was evidenced by various workarounds created by staff members in the existing process. For this reason, all staff should be encouraged to report inefficiencies for continuous quality improvement. Future interventions should further develop the oral chemotherapy policy and procedure outline developed from this project. New information about the oral chemotherapy medication, the need of patients, and change in providers should also be incorporated into an evolving workflow. Further consideration of the implementation of this adherence policy across the Providence Health Systems with focus on regional differences will help with a system wide standardization.

Conclusion

While the availability of oral targeted agents has increased over the last decade mainly because of their convenience, they also have their unique challenges. With the changing landscape of cancer treatment, practices need to adapt by creating standard policy and procedures. They should also generate standard education materials and allow adequate time for patient education. Lastly, clinics must maintain staff knowledge of oral

oncolytics. By incorporating all members of the healthcare team, including pharmacy staff to assist with medication management, clinics can improve patient education and support. These changes in totality can result in improved patient adherence and treatment outcomes. Oral chemotherapy can only be effective if adherence is optimized. While this quality improvement project was met with many barriers, it was an essential first step in improving the way this clinic delivers oral chemotherapy.

Figure 1: The new protocol for the oral chemotherapy workflow in the local clinic

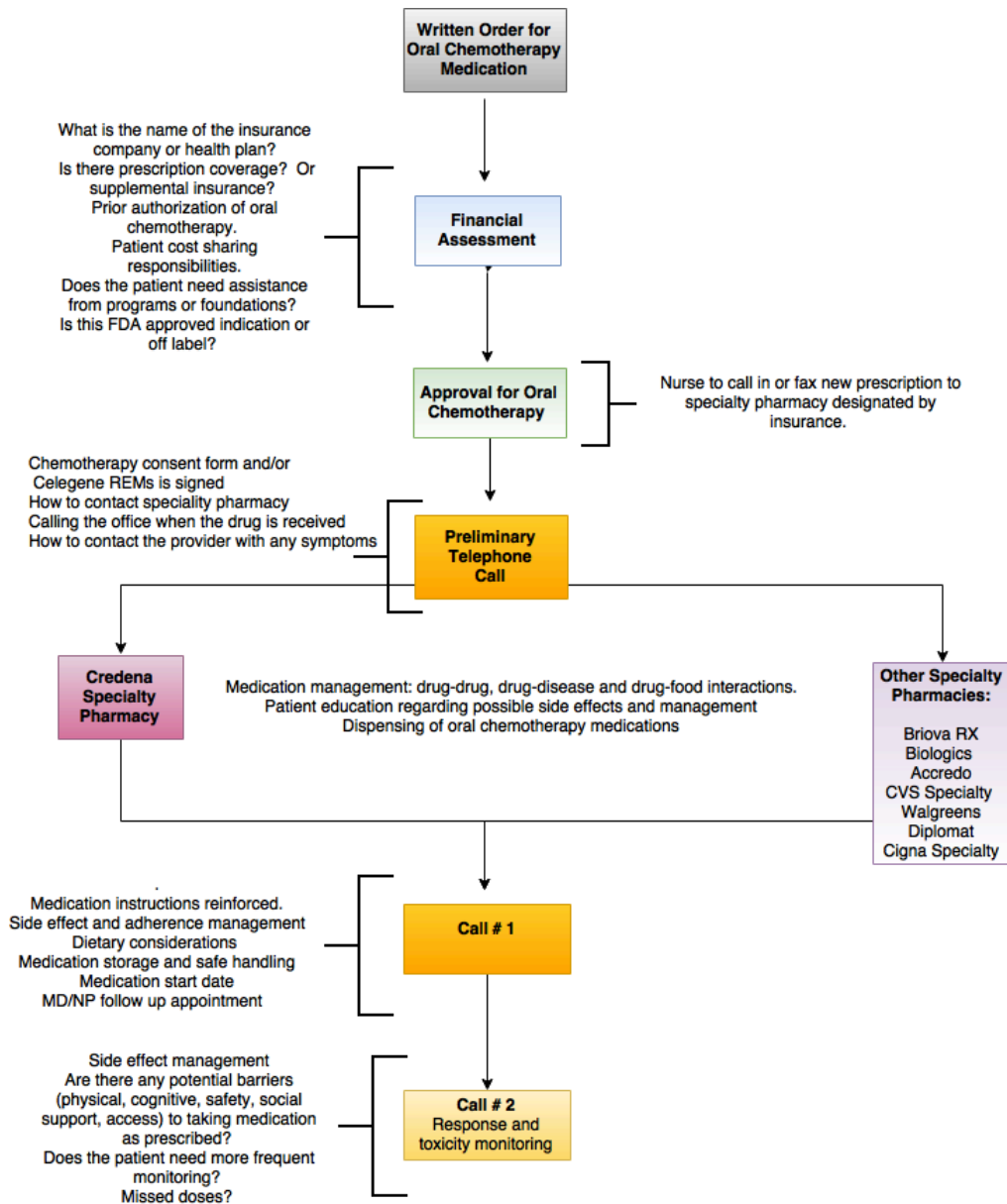


Table 1: Survey questions

1	In my practice setting, when a patient receives a prescription for an oral anti-oncologic, there is a good mechanism for informing nurses in the practice (e.g., flag chart, keep names on a list).
2	In my practice, there are formal oral drug triage plans for symptom management and follow-up.

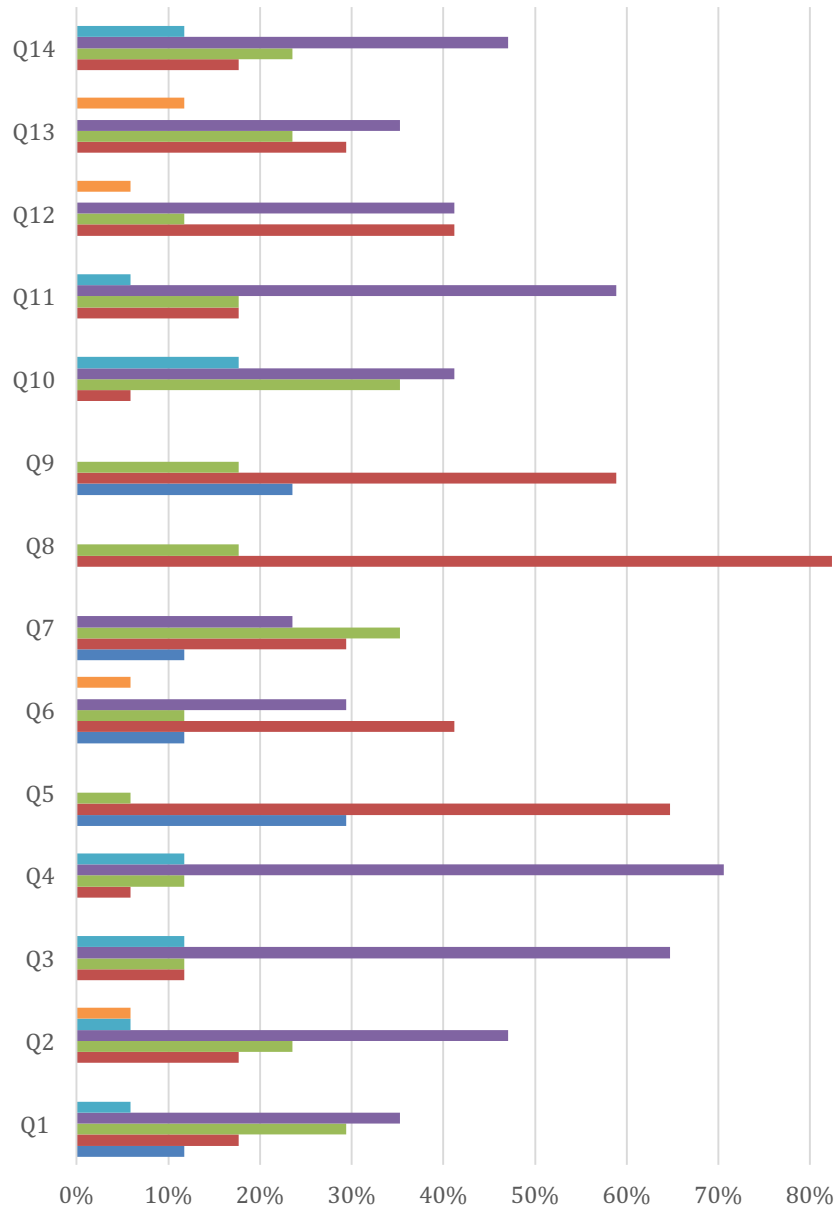
3	When a patient is prescribed an oral anti-oncolytic, there is sufficient time for educating the patient and family about the medication (dosing, storage, precautions, management of side effects, when to call the office, and disposal).
4	The practice has effective methods for tracking adherence to oral anti-oncolytic medications.
5	If drug information education sheets for nurses and/or patients were standardized, patient education and adherence would improve.
6	I have enough knowledge about oral chemotherapy medications to provide safe care for patients.
7	One of the largest barriers to patient adherence to oral anti- oncolytic medication is side effects.
8	One of the largest barriers to patient adherence to oral anti- oncolytic medication is complex instructions.
9	One of the largest barriers to patient adherence to oral anti- oncolytic medication is cost.
10	There is a system-based approach for detecting prescription errors for oral oncolytics?
11	My practice has adequate educational materials for patients taking oral chemotherapy and their families (pamphlets, information sheets, videos, hotline for questions).
12	I know when patients on oral chemotherapy medication are likely to develop the most unpleasant or serious adverse reactions to the oral medication (e.g., 24 hours after the first dose, two weeks after the first dose).
13	My practice has policies, procedures, and/or guidelines that are specifically for patients taking oral chemotherapy medications
14	I am reasonably sure that if a patient stops taking his or her oral anti-oncolytic medications, key personnel in the practice will know.
<p><i>Note: Reprinted courtesy of the Oncology Nursing Society (ONS) from “Current Practice Patterns for Oral Chemotherapy: Results of a National Survey” by Janna C. Roop & Horng-Shiuann Wu, 2014, Oncology Nursing Forum, 41(2), 185-194. Copyright 2014 by ONS. All rights reserved.</i></p>	

Table 2: Demographics of the survey participants

Sample Demographics (n=17)		
Characteristics	n	%
Gender		
Female	15	88

Male	2	12
Age		
18-29	3	18
30-49	9	53
50-64	5	29
65 and older	0	0
Education		
High School	0	0
Some College	1	6
Associate	2	12
Bachelors	8	47
Masters	4	24
Doctorate	1	6
Professional	1	6
Years in Oncology		
Less than 1 year	0	0
1 to 5 years	4	24
6 to 10 years	5	29
11 to 15 years	2	12
More than 15 years	6	35
Oral-chemo Experience		
Less than 1 year	4	25
1 to 5 years	7	44
6 to 10 years	2	13
11 to 15 years	1	6
More than 15 years	2	13
Hours worked per week		
35 or more hours	15	88
35 or less hours	2	12

Figure 2: Responses to the survey questions



	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14
other	0%	6%	0%	0%	0%	6%	0%	0%	0%	0%	0%	6%	12%	0%
strongly disagree	6%	6%	12%	12%	0%	0%	0%	0%	0%	18%	6%	0%	0%	12%
disagree	35%	47%	65%	71%	0%	29%	24%	0%	0%	41%	59%	41%	35%	47%
neither agree or disagree	29%	24%	12%	12%	6%	12%	35%	18%	18%	35%	18%	12%	24%	24%
agree	18%	18%	12%	6%	65%	41%	29%	82%	59%	6%	18%	41%	29%	18%
strongly agree	12%	0%	0%	0%	29%	12%	12%	0%	24%	0%	0%	0%	0%	0%

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