

Practice Model: Establishing and Running an Oral Chemotherapy Management Clinic

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ABSTRACT

Oral anticancer agents, while potentially more convenient and better tolerated than traditional intravenous therapy, come with significant concerns of noncompliance, adverse effects, and high cost. This presents an opportunity for health-care practitioners to develop a method to educate and support patients who are placed on these agents. To provide a detailed example of a currently established oral chemotherapy clinic and provide direction toward setting up a new clinic at other institutions. A description of the establishment of the clinic, how it is run and

examples of interventions are provided. Establishment of an oral chemotherapy clinic run by supportive oncology practitioners is feasible and may provide added value to existing oncology care. It can also provide an opportunity to further involve health-care trainees in patient care.

Key words: Cancer, oncology pharmacy, oral anticancer therapy, oral chemotherapy, phone clinic

Introduction

Traditional intravenous (IV) chemotherapy has been the longtime standard for treatment of patients with cancer. There are defined administration standards, safety protocols, and coordinated care for patients being treated in infusion centers and hospitals with these medications. The introduction of novel oral agents is causing a paradigm shift in the management of cancer. Oral anti-cancer agents are an attractive option for patients and are quickly being approved in a record setting pace with almost twenty new

approvals over the past 3 years.^[1] Oral agents offer patients less office visits, a different side effect profile and the ability to feel like they have more control over their therapy.^[2]

While this may be a great option for a number of patients, oral therapies are often a more complex alternative. Some regimens have a complex administration schedule, whereas others have high pill burdens and require daily dosing and compliance. This puts a great deal of responsibility on the patient and caregiver for maintaining appropriate therapy

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and addressing side effects as they arise. The safety net of a clinic visit to provide detailed education, administer IV medications, and an assessment of side effects is now handed over to the patient and caregiver, oftentimes from a provider in a very busy clinic. Patients are seen less frequently in office visits and opportunities are missed to triage and treat symptoms as they arise.^[3]

Given the complexities and risks involved with oral chemotherapy, frontline counseling is crucial to ensure proper education is given to the patient and caregiver. This is an excellent opportunity for pharmacy staff to play a critical role in a patient's success with therapy. Pharmacists can explain the risks of therapy, possible benefits received, the need for compliance, and the seriousness of side effects, as well as offer strategies for treating these side effects and allow for an open and comfortable dialog to take place between the patient and treatment team.^[4]

The pharmacy team at the Malcom Randall Veterans Affairs (VA) Medical Center, has established a pharmacy managed oral chemotherapy clinic. The following will outline the practices of the oral chemotherapy clinic, and then follow up with suggestions on establishing an oral chemotherapy clinic at other sites.

The Malcom Randall VA Medical Center is located in Gainesville, Florida, USA. This institution offers both in- and out-patient care to a region covering North Florida and South Georgia. The oncology section employs a multidisciplinary team of physicians, pharmacists, nurses, nurse practitioners, physician assistants, patient care coordinators, social workers, program support assistants, pharmacy residents, and registered pharmacy interns who are in their fourth professional year of pharmacy school. There is also a team of 15 hematology/oncology fellows from the University of Florida that provide much of the patient care.

Numerous safeguards are in place in our facility for IV chemotherapy, including double checks for dose calculations and preparations and frequent clinic visits to assess tolerability. As is recommended by the American Society of Clinical Oncology and Oncology Nursing Society Chemotherapy Administration Safety Standards,^[5] all IV chemotherapy patients are evaluated with a questionnaire assessing treatment related toxicities with each infusion. This is mostly completed by pharmacy staff, including registered pharmacy interns, residents or pharmacists. Toxicities are documented in the electronic chart and providers are contacted with urgent concerns.

In 2009, oral chemotherapy was becoming more prevalent and it was recognized that we did not have these same safeguards for safe administration of oral anticancer agents. New medications were dispensed to patients who

often returned a month later and we realized they were not taking the medication correctly or complained of various side effects that had persisted for quite some time without the prescribing provider's knowledge. Examples include: Hand/foot syndrome from capecitabine that had progressed to where the patient was unable to walk, severe untreated rash from erlotinib and newly elevated blood pressure from sorafenib. Patients were also unaware of how to manage these side effects if they recurred. At this time, it was decided that the patients needed detailed counseling on these drugs before dispensing. Members of the oncology pharmacy staff were asked to counsel patients on any new prescription for oral chemotherapy.

Establishment of the Clinic

While initial counseling could help patients become more educated about their new medication, our oncology pharmacy group recognized that a method for assessing whether the information was retained and implemented once the patient and their caregiver returned home was needed. It was determined that a weekly phone call to follow-up with the patient would meet this need. As patients were already being scheduled for follow-up with their oncology provider in 4 weeks' time, the phone calls were designed to be conducted for the first 3 weeks of therapy, in the crucial time immediately after the prescription of the medication, with subsequent follow-up to be done with regular monthly oncology clinic visits. To standardize the content of the phone calls and assure continuity of follow-up regardless of the health-care team member calling, an oral chemotherapy assessment questionnaire was developed [Box 1]. The questionnaire first documents when the patient began the drug and then assesses compliance and proper administration. This allows the caller to ensure the patient is taking the medication as prescribed and as recommended in regards to food and timing. Second, the assessment delves into potential side effects that are common to the oral chemotherapy agents used in a variety of disease states. Finally, callers are asked to add a short assessment and plan. This questionnaire was built as a template into our electronic medical record for ease of documentation.

Once support for the clinic was established from leadership at our institution, oncology staff was educated verbally and through E-mail communication that pharmacy should be contacted anytime a patient was to be prescribed a new oral chemotherapy medication. To ensure patients were not missed, oral chemotherapy agents were marked as "pharmacy only entry" meaning that it required review and order placement by an oncology pharmacist before patient dispensing.

Box 1: Sample Interview Questionnaire

Oral chemotherapy assessment:
 Patient name: _____ Date: _____
 Diagnosis: _____
 Oral chemotherapy regimen: _____
 Start date: _____ Radiation start date (for capecitabine): _____
 Compliance assessment:
 Correctly states dosing instructions: Yes () No ()
 Missed doses: Yes () No () How many missed? _____ Reason? _____
 Takes: With food () Without food ()
 Side effect assessment:
 Sore mouth or throat: Absent () Soreness () Ulcerations () White patches ()
 Bleeding: Yes () No ()
 Site: _____
 On coumadin: Yes () No ()
 Diarrhea: Yes () No ()
 Constipation: Yes () No ()
 Bladder: None () Dysuria () Frequency () Hematuria ()
 Incontinence ()
 Pain:
 No pain 0 1 2 3 4 5 6 7 8 9 10 worst pain
 Current pain level: _____
 Pain medications: _____
 Effective control?: _____
 Fever: Yes () No ()
 Fatigue: Quite rested 0 1 2 3 4 5 6 7 8 9 10 completely exhausted
 Nausea: None () Mild () Moderate () Severe ()
 Vomiting: Yes () No ()
 Appetite: None () 25% () 50% () 75% () 100% ()
 Cough: Yes () No () If yes, productive? Yes () No ()
 SOB: None () Mild () Moderate () Severe ()
 On oxygen?: Yes () No ()
 Motor weakness:
 None: Yes () No ()
 Paresthesias (tingling/numbness): Yes () No ()
 Ataxia (unsteady gait): Yes () No ()
 Visual/auditory disturbances: Yes () No ()
 Blood pressure monitoring (for TKIs only): Yes () No ()
 Last reading: _____
 Assessment/plan: _____

Before the clinic was formally established, follow-up was difficult as there were no scheduled appointments and patients were often missed. The busy nature of an oncology pharmacy work area often led to prioritizing of tasks, with phone call follow-ups being moved further down the list. It was decided that a more formal clinic should be established if it was to be effective. Paperwork was completed to establish a formal telephone clinic, and it was decided to schedule phone appointments in the afternoon 2 days/week. As the clinic grew, this was expanded to 3 days/week.

Description of our Model

Three dedicated oncology pharmacists are on staff at our institution. In addition, there are two pharmacy

interns assigned to an oncology rotation each month. As the initiative for the clinic was started by pharmacy, it was determined that a member of the pharmacy staff would conduct the initial counseling as well as the phone follow-up. As this is a teaching institution, the phone calls and much of the initial counseling sessions are primarily conducted by the pharmacy interns (4th year pharmacy students), which allows them the opportunity to enhance their patient communication skills. Before any initial counseling, pharmacy interns are trained in a 1 h oral chemotherapy discussion session with a pharmacist preceptor where they learn about and practice counseling on the most commonly used oral chemotherapies including but not limited to: Abiraterone, enzalutamide, pazopanib, sunitinib, sorafenib, erlotinib, afatinib, and capecitabine. This discussion includes proper medication administration, common side effects, and side effect management strategies. Once the teaching pharmacist is confident in their abilities and knowledge base, the interns may begin participating in the clinic.

When patients are initially counseled, they are provided with in-depth patient-friendly handouts to ensure they have printed information available at home. Oftentimes, these are obtained from the manufacturers’ websites that usually have dedicated patient information sections. Various drug information resources also have such handouts. Verbal counseling follows the American Society of Health-System Pharmacists Guidelines on Patient Education and Counseling.^[6] Patients are instructed how to take the medication, including: How many pills, how many times/day, whether the medication should be taken with or without regards to food, and how to handle missed doses. If a medication has to be taken in certain regard to food, it is useful to establish with the patient how that drug will fit into their daily routine, and what time of day would be best for the patient to remember it. For example, if a medication should be taken on an empty stomach, at least 1 h before or 2 h after eating, then it could be explained to the patient that a proper time could be on first waking up and waiting an hour to eat breakfast, or at bedtime, at least 2 h after the evening meal. The patient can then pick which fits better with their routine, and have an idea of the exact time he or she will take the medication. Importance of compliance should be emphasized. The patient’s current medication list is reviewed for any potential drug interactions and patients are further counseled on common problematic foods and drinks (i.e., grapefruit juice interactions with cytochrome P450 3A4 metabolized medications). Common and serious side effects are also discussed, including how to manage mild side effects at home and when to contact their provider or seek medical attention. Patients are given

direct contact information for pharmacy staff and notified of the best contact number to reach their provider. Finally, proper medication handling and disposal are outlined. It is especially important if the medication will be handled or administered by a caregiver to inform of proper handling of the medication by someone other than the patient, to reduce caregiver exposure.

Following the counseling, a note documenting the counseling is entered into the electronic chart and follow up appointments for weekly phone assessments are scheduled for the 1st month after the patient starts the oral chemotherapy. Generally, two to three phone follow-ups are scheduled, depending when the patient is scheduled to return for provider visit. The involvement of pharmacy interns in these phone assessments is beneficial to both the trainees and the medical center. Trainees are given a valuable learning opportunity, and medical center staff receives assistance with workload in an already busy environment.

During phone follow-ups, the pharmacy team member administers the oral chemotherapy questionnaire [Box 1], which generally takes 5–10 min to complete for a patient who is tolerating the medication well. If multiple problems are uncovered, the assessment may take longer. The questionnaire covers compliance, dosing instruction and various common side effects. If a side effect is noted, measures taken by the patient to manage it are further explored. For example, if nausea is reported: Has the patient taken the available as-needed nausea medication? Issues are triaged to determine if it is appropriate to treat at home versus notifying a provider, or advising the patient to come to the emergency room. If appropriate for home treatment and no measures have been taken, patients are counseled on how to manage the side effect. If home treatment is not appropriate, providers are contacted to discuss the issue and refer the patient for appropriate follow-up.

Description of Interventions

In 2010, a facility quality control project was conducted to determine the types of interventions being made. This project was approved by the Institutional Review Board at the University of Florida and the research and development committee at the North Florida/South Georgia Veterans Health System. A small sample of 46 follow-up telephone encounters were evaluated and 67 pharmacist driven interventions were quantified. Medications such as clindamycin gel, ondansetron, polyethylene glycol and oxycodone were prescribed to manage side effects. Medication refills were requested and provided for both side effect management medications as well as primary care maintenance medications. Medication counseling

was provided for ongoing patient management included re-enforcing key points about the oral chemotherapy agent and supportive care medications. Side effect management counseling was provided on how to adjust laxatives to manage diarrhea/constipation, taking nausea medication before meals, instructions on caring for dry skin, and the importance of monitoring temperature and blood pressure. Oncology providers were contacted either for clarification of order and/or to discuss management of patient. Patients were instructed to hold medication due to hand/foot syndrome and due to increased side effects. Patients were advised to seek medical attention as a result of increased shortness of breath, urinary tract infection, severe rash, and headache. Appointments were changed to reduce travel burden for patients and their caregiver. Other interventions included mailing a blood pressure cuff for a patient on a tyrosine kinase inhibitor, psychology consult and referral to the VA suicide hotline for a suicidal patient, and contacting a hospice center to adjust patients long acting pain medications.

The number of phone follow-ups has remained fairly steady at around 200/year. An increase in follow-ups occurred in 2016 with 200 follow-ups conducted in 10 months. The physicians and oncology team at our medical center have embraced the oral chemotherapy management clinic and recognize it to have a valuable impact. At times, pharmacy services are even requested to call established patients to follow up on particular side effects, or to help with compliance issues. Although not formally studied, physicians have also come to appreciate that pharmacy education for new patients can save them time during a consult.

Discussion

Standardization of the telephone interview with use of the questionnaire allows great flexibility in the conduction of the phone follow-up. Our model involves mainly pharmacy staff, however any health-care practitioner who is familiar with the oral chemotherapies could feasibly conduct follow-up. This could potentially include nurses, pharmacists, pharmacy technicians, physician extenders, physicians, or patient care coordinators. Trainees such as students, residents, and fellows could also participate, providing a valuable learning experience while also decreasing work load of full time staff. Before implementing the clinic, it should be discussed and determined which health-care practitioner would be best suited to conducting follow-up at your institution. A combination of practitioners could also be utilized to distribute time commitment.

It is recommended to develop an action plan for the establishment and management of the oral chemotherapy

assessment clinic before pitching the idea to department leadership. Be prepared with expected workloads, who is going to call, and a sample questionnaire that will outline exactly what will be followed up on. It is also important to outline how issues will be triaged and how providers will be contacted for emergent issues. Once a plan is in place, schedule a meeting with involved department heads, such as the chief of oncology, and nursing pharmacy to discuss. It is important to note that such a clinic is not taking the place of regularly scheduled oncology visits. It is meant to supplement these visits, in order to provide safe and effective oncology care for patients who are prescribed oral anticancer medications. A discussion should also be had regarding the best way to capture workload and possibly establish a billing procedure in instances where pharmacists can participate in this practice. This will help administration understand the benefits of a pharmacy managed oral chemotherapy clinic.

Each new endeavor is not without challenges. Initial challenges were identified in our follow-up process. Once the formalized appointment system is established, compliance in making scheduled phone calls must be 100%. Furthermore, any clinic that is run by phone faces challenges in getting in touch with patients. Oftentimes, it may take several phone calls to reach a patient, and on occasion a patient is not able to be reached at all. On busy weeks, it can be difficult to complete all scheduled phone calls in addition to other duties. However, as the phone calls must be made, utilizing trainees (students and residents) under appropriate supervision is very helpful in ensuring completion, while also providing a good learning experience for the trainees.

This is a limited description of an existing clinic. Follow-up data have not been officially obtained for our particular clinic to evaluate the effectiveness of our implementation. Future studies assessing the impact of the clinic on cost savings, reducing hospital admissions, improving compliance, and reducing the length of time of physician visits would be useful to provide rationale for the establishment of future similar clinics.

Future Directions

As the number of oral chemotherapy medications continues to rise, oncology practitioners will be challenged to evolve practice management strategies to best care for patients on these agents. Future directions in our clinic may include utilizing technology to better follow up with patients remotely. Many chemotherapy side effects are dermatologic related, including rashes and hand-foot syndrome. As technology now allows for virtual visits, perhaps we could better serve patients by also offering

telehealth appointments, to allow for visual remote visits with patients and better assessment of described side effects. As the number of patients on oral chemotherapy increases, we may also need to further expand the telephone clinic to accommodate more patients.

It is currently being predicted that the growth in the number of oncologists is not going to be enough to meet the expected increase in demand for oncology services. While improved survival rates and an aging patient population increase demand, an aging and retiring oncology workforce as compared to the number of available fellowship positions and graduating new practitioners is expected to decrease the number of practicing oncologists.^[7] This presents an opportunity for other oncology practitioners such as oncology nurses, pharmacists, physician extenders, nurse navigators, and others to assist in patient care management. Oral chemotherapy management clinics such as ours provide one example of implementation of interdisciplinary patient care.

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Conflicts of interest

There are no conflicts of interest.

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