Are Patients on Oral Chemotherapy in Your Practice Setting Safe?

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The use of oral chemotherapy is expected to more than double in the next several years. With the increase in use of oral chemotherapy and in patient responsibility, the role of the oncology nurse must change to ensure proper management. Nurses must teach patients how to correctly and safely take oral chemotherapy, help manage side effects, and research and monitor complications such as medication and food interactions, cost issues, safety, and patient adherence.

Since 2005, 10 oral chemotherapy medications have been introduced into the market (see Table 1). This trend will likely continue, and the number of available oral chemotherapy medications is expected to more than double in the next several years (Weingart et al., 2008). In fact, 25% of the 400 cancer chemotherapy agents currently in development are oral medications (Bowers, Silberman, & Mortenson, 2002; Moore, 2007; Thomas, Cahill, Mortenson, & Schoenfeldt, 2000; Weingart et al., 2008). The growing use of oral chemotherapy has affected all aspects of oncology profoundly; it has created significant safety and adherence issues and shifted some of the traditional roles and responsibilities of oncologists, nurses, and pharmacists to patients and caregivers (Weingart et al., 2008). The shift in responsibilities has many oncology practice administrators scrambling to find new and better ways of utilizing nursing staff to manage and support patients.

From 1993–2002, 25 deaths and 26 cases of serious injury associated with errors in prescribing or taking oral methotrexate were reported to the National Patient Safety Agency in the United Kingdom. Most of the errors were attributed to patients not receiving sufficient information on how to properly take the medications (Mayor, 2003).

Many people incorrectly believe that oral chemotherapy medications are less toxic than IV chemotherapy medications. Chemotherapy medications, whether oral or IV, typically have a narrow therapeutic index, which places patients taking them at increased risk for harmful effects (Bartel, 2007; Birner, 2003; Griffin, 2003; Weingart et al., 2008). Because oral and IV chemotherapy medications have the potential to cause harm, nurses must be involved in the care of patients receiving either form. With oral chemotherapy, patients and caregivers must be thoroughly educated and understand the potential dangers associated with taking such medications. Having nurses designated to care for such patients is a way to ensure patient safety during oral chemotherapy treatment. Nurses designated to care for people taking oral chemotherapy can help patients and caregivers understand the importance of adhering to oral chemotherapy regimens, recognize side effects to report immediately, and safely administer and handle oral chemotherapy.

Nurses who are familiar with the characteristics of various oral chemotherapy medications are in a better position to communicate accurate and detailed patient education that will provide foreseeable benefits of oral therapy while minimizing risks associated with treatment (Birner, 2003). As Moore (2007) wrote, “Oncology nurses are uniquely positioned to step into new roles emphasizing patient and family education and support. Individualized patient support will be vital in providing quality patient and family education as well as side-effect management during oral chemotherapy” (p. 113). Oral chemotherapy requires a significant amount of nursing time for patient education, especially at the beginning of an oral chemotherapy regimen (Weingart et al., 2008).

At a Glance

- Patients taking oral chemotherapy are just as much at risk for harmful side effects as those receiving IV forms.
- Patient education is the key to successful treatment with oral chemotherapy.
- Having dedicated nurses caring for patients receiving oral chemotherapy may improve patient safety as well as adherence to oral chemotherapy regimens.

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Creating the Oral Chemotherapy Nursing Role

Because of the increase in oral chemotherapy use, administrators and the five physicians at a hospital-based, not-for-profit clinic in central North Carolina decided to take a proactive

Table 1. Oral Chemotherapies

<table>
<thead>
<tr>
<th>DATE</th>
<th>NAME AND MANUFACTURER</th>
<th>STRENGTH(S)</th>
<th>INDICATIONS</th>
<th>WEB SITE AND SOURCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2009</td>
<td>Pazopanib (Votrient™, GlaxoSmithKline)</td>
<td>200 mg</td>
<td>Advanced renal cell carcinoma</td>
<td><a href="http://www.votrient.com/index.html#">www.votrient.com/index.html#</a></td>
</tr>
<tr>
<td>October 2007</td>
<td>Topotecan (Hycamtin®, GlaxoSmithKline)</td>
<td>0.25–1 mg</td>
<td>Relapsed small cell lung cancer</td>
<td><a href="http://www.hycamtin.com">www.hycamtin.com</a></td>
</tr>
<tr>
<td>October 2007</td>
<td>Nilotinib (Tasigna®, Novartis Oncology)</td>
<td>200 mg</td>
<td>Philadelphia chromosome–positive chronic myelogenous leukemia</td>
<td><a href="http://www.us.tasigna.com/index.jsp">www.us.tasigna.com/index.jsp</a></td>
</tr>
<tr>
<td>March 2007</td>
<td>Lapatinib (Tykerb®, GlaxoSmithKline)</td>
<td>250 mg</td>
<td>Breast cancer</td>
<td><a href="http://us.gsk.com">http://us.gsk.com</a></td>
</tr>
<tr>
<td>October 2006</td>
<td>Vorinostat (Zolinza®, Merck &amp; Co., Inc.)</td>
<td>100 mg</td>
<td>Cutaneous T-cell lymphoma</td>
<td><a href="http://www.zolinza.com/vorinostat/zolinza/consumer/cutaneous-t-cell-lymphoma-treatment.jsp">www.zolinza.com/vorinostat/zolinza/consumer/cutaneous-t-cell-lymphoma-treatment.jsp</a></td>
</tr>
<tr>
<td>June 2006</td>
<td>Dasatinib (Sprycel®, Bristol-Myers Squibb)</td>
<td>20–50 mg</td>
<td>Chronic myelogenous leukemia and Philadelphia chromosome–positive acute lymphoblastic leukemia</td>
<td><a href="http://www.sprycel.com">www.sprycel.com</a></td>
</tr>
<tr>
<td>January 2006</td>
<td>Sunitinib (Sutent®, Pfizer Inc.)</td>
<td>12.5 mg</td>
<td>Gastrointestinal stromal tumor and advanced renal cell carcinoma</td>
<td><a href="http://www.sutent.com">www.sutent.com</a></td>
</tr>
<tr>
<td>December 2005</td>
<td>Lenalidomide (Revlimid®, Celgene Corporation)</td>
<td>5–10 mg</td>
<td>Myelodysplastic syndromes and multiple myeloma</td>
<td><a href="http://www.revlimid.com">www.revlimid.com</a></td>
</tr>
</tbody>
</table>

Note. See full prescribing information for each product for indications and recommended dosages.

2008). Accurate and detailed patient education about oral chemotherapy promotes patient safety, optimal dosing, and adherence to the treatment plan (Hartigan, 2003). Despite the importance of patient education, most insurance companies, including Medicare, do not reimburse for nursing time spent educating patients. Lack of reimbursement for patient education may discourage many practice administrators from employing nurses whose sole responsibilities are educating patients and monitoring adherence to oral chemotherapy regimens.

The purpose of this article is to describe the development of an oral chemotherapy nursing position as well as role implementation in an ambulatory medical oncology setting. The desired outcome for this position is to improve medication safety and adherence for patients taking oral chemotherapy medications.

Literature Review

A literature search was conducted to identify published articles on the management of oral chemotherapy medications. Databases used for the literature search included CINAHL®, MEDLINE®, Health and Medical Complete, ProQuest Central, PubMed, Sage Journals Online, and Ovid Journals Online. The terms used in the search were chemotherapy, oral chemotherapy, and nursing roles. No date limits were specified. A total of 32 articles were retrieved and determined to be relevant. Articles were considered relevant if the title mentioned safety, side effects, adherence, patient education, or nursing roles pertaining to oral chemotherapy. The key themes from the articles were specific drug information, safety, side-effect management, drug interactions, food interactions, medication adherence, and financial information. The importance of nurses educating patients regarding oral chemotherapy was discussed in several articles. Mention of an oral chemotherapy nursing role in the literature was scarce. An article by Barefoot, Blecher, and Emery (2009) explained a nursing model used in a clinic for patients on oral chemotherapy. The model described care provided by an advanced practice nurse (APN) for all patients prescribed oral chemotherapy. The APN was responsible for patient education, monitoring, and support in the defined patient population. At this time, no standard nursing models exist to guide the direct care of patients receiving oral chemotherapy. With the use of oral chemotherapy expected to rise, the idea of designated nursing support for patients taking oral chemotherapy requires further exploration.
approach to the new paradigm in oncology treatment. The practice chose to implement the role of an oral chemotherapy nurse to ensure adequate education and support for patients prescribed oral chemotherapy. During the implementation process, the administrators decided to utilize an existing full-time nursing position from the infusion area for the role of oral chemotherapy nurse. Prior to implementation of the role, seven infusion nurses carried a patient load of four or five patients per day. Since role implementation, six nurses work in the infusion center, with an increase in patient load by one patient per day. The infusion nurses have taken on the additional patient responsibility willingly because they are acutely aware of and support the need to ensure patient safety during chemotherapy treatment, regardless of the route.

Initiating the Role for Patients Currently Taking Oral Chemotherapy

Initially, the oral chemotherapy nurse reviewed charts to identify patients currently prescribed oral chemotherapy. Once they were identified, they scheduled an appointment with the oral chemotherapy nurse to review proper dosage, safe handling techniques, recognition of critical side effects to report, dietary restrictions, drug interactions, and medication adherence. For ongoing care, patients are seen by a physician and the oral chemotherapy nurse prior to each cycle, or monthly if medication is taken daily. After the initial visit with the oral chemotherapy nurse, the focus for subsequent visits includes review and documentation of adherence, assessment for side effects and interventions used to manage toxicities, and assurance that correct dose and schedule were followed. The nurse and oncologist collaborate to ensure appropriate follow-up care. Prior to completion of the office visit, patients are reminded to contact the oral chemotherapy nurse for any problems or questions regarding treatment.

Care for Patients Prescribed Oral Chemotherapy for the First Time

One of the most important functions of the oral chemotherapy nurse is working with patients being prescribed oral chemotherapy for the first time. At the initial meeting, the nurse assesses the patient for ability and willingness to adhere to the prescribed regimen. According to Moore (2007), a strategy for promoting adherence is to assess a patient’s or caregiver’s motivation to follow instructions as well as perceptions of risks and benefits of oral therapy. The following questions may help facilitate the process.

- Is the patient a highly motivated person who can assume the increased responsibility that comes with self-administration of oral chemotherapy medications?
- Does the patient want to actively participate in his or her treatment?
- Is the patient mentally and cognitively able to be in control of his or her own oral chemotherapy regimen?

If the nurse determines that the patient or caregiver is able to handle the increased responsibility that comes with oral chemotherapy, then the nurse proceeds with planning the educational session. According to Moore (2007), the best way to effectively address the individual needs of patients and families is through well-planned and thorough patient and family education. When setting up a patient educational session, the oral chemotherapy nurse makes an appointment for the patient to return on a different day for a 60- to 90-minute educational session. To enhance the learning experience, the nurse schedules the teaching session on a day when the patient is not seeing a physician or receiving chemotherapy (Moore, 2007). Depending on patient preference, educational material may be given beforehand so that the patient or caregiver can prepare. In preparation for the educational session, the nurse orders the chemotherapy medication(s) through a specialty pharmacy, prepares a medication administration calendar, and obtains patient teaching information specific to the medication(s) prescribed. Studies support the use of individualized materials to help reinforce education presented by the nurse (Moore, 2007). Various resources are widely available to assist patients beginning oral chemotherapy (www.UpToDate.com, www.Chemocare.com, www.cancer.gov/DRUGDICTIONARY/, and the American Cancer Society’s “Guide to Cancer Care”). Healthcare providers should use those that provide simple, clear, and concise education. If the facility permits, and after careful review, use handouts developed by pharmaceutical companies. If forms are developed at the healthcare facility, limit the important information to a one- or two-page handout to be given to a patient during the educational session (see Figure 1). This handout should include medication name, dosage, frequency, side effects, when to call the physician, how to contact the oral chemotherapy nurse during clinic hours, and how to contact the physician when the clinic is closed. Having all of the important information on a short handout and placing it in a visible location allow patients to access the information quickly. At the completion of the educational session, the patient should be asked to reiterate the key points to confirm understanding of the education provided.

Initial Educational Session

During the initial educational session, the oral chemotherapy nurse teaches the patient how to correctly take the oral chemotherapy medication(s). This includes special instructions such as whether the medication should be taken on an empty or full stomach. If the patient has a complicated oral chemotherapy regimen, the patient is instructed to double- and triple-check the dose each and every time he or she takes the medication. Oral chemotherapy calendars are especially important for patients who have complicated chemotherapy regimens. If used properly, calendars can help simplify complicated chemotherapy regimens, help patients remember whether they have taken their medication(s), and prevent or reduce errors in dosing. Figure 2 is an example of a medication calendar created in Microsoft® Excel®. Various Web sites are available to healthcare professionals and patients to help them manage medication administration. One such site, MedActionPlan.com, allows healthcare professionals to create quick, easy, and simple medication calendars. In addition to the calendar, MedActionPlan.com allows nurses to create a one-page summary of a patient’s current treatment...
Take within 30 minutes of eating a meal with a full glass of water.

**Side Effects**
Diarrhea, nausea, vomiting, mouth sores, abdominal pain, upset stomach, constipation, loss of appetite, dehydration, nail problems, minimal hair loss, tiredness, weakness, dizziness, headache, trouble sleeping, taste problems, joint pain, muscle pain, and red, dry, peeling, painful feet and hands

**Important Safety Information**
- This medication is considered a chemotherapy medication and may cause harm. People other than the patient must not touch the medication. Medication can be transferred from the bottle, to a medicine cup, and then to the patient’s mouth without contacting the skin.
- This medication should be kept in the original container marked with the medication’s name and dosage.
- Patients should wash their hands immediately after touching the medication.
- Do not open, crush, break, cut, or chew this medication without talking to an oncology nurse or pharmacist. If the tablet is accidentally damaged, do not inhale the powder. If it comes into contact with your skin, wash right away with soap and water.
- Medication must be disposed of properly. Bring contaminated or unused medication to the clinic for proper disposal.
- Do not share your medication with anyone.
- Take your medication around the same time each day.
- Do not double dose. Take missed doses as soon as possible, but do not take it near the time that your next dose is due.
- Do not change your dose or stop taking this medication without talking with your physician.
- Store medication at room temperature, do not use it after the expiration date on the bottle, and keep it out of reach of children.

**Information Concerning Side-Effect Management**
- Indigestion: You may take over-the-counter drugs for indigestion. Such drugs must be taken two hours before or two hours after capecitabine.
- Diarrhea: Inform your physician if you have four additional bowel movements beyond your normal pattern per day or diarrhea at night. If you are having six to eight loose stools per day, try eating bananas, rice, apples, and toast for 24 hours, then try reintroducing your normal foods back into your diet. Remember to drink plenty of fluids, especially sports drinks to replace the electrolytes you lose with diarrhea.
- Keep hands and feet clean, dry, and well moisturized with lanolin-based emollients or creams.
- Rinse mouth every three hours with the following mixture: one-quarter teaspoon baking soda, one-eighth teaspoon of table salt, and 1 cup of warm water. To make a larger batch, mix 1 teaspoon of salt, 2 teaspoons baking soda, and one quart warm water. Make a fresh batch every 24 hours.

**When to Call the Doctor**
- If you have pain, redness, swelling, or sores in your mouth
- If you have pain, swelling, or redness on your hands or feet that prevent or interfere with normal activity
- If you have an additional four bowel movements each day beyond what is normal for you or any diarrhea at night
- If you vomit more than once in a 24-hour period, lose your appetite, or eat much less food than normal
- If you have a temperature of 100.5°F or greater or other signs of infection

**Contact Information**
Clinic number and emergency number: ___________________________
Pharmacy name and number: ________________________________

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Figure 1. Capecitabine Patient Education

*Note.* Based on information from Genentech, Inc. (n.d.). Figure used courtesy of Rex Hematology Oncology Associates.
Weingart et al., 2008). Healthcare professionals and caregivers should wear gloves when handling all bodily fluids. Some oral chemotherapy medications remain in the body for five to seven days after the regimen is completed. Therefore, standard precautions should continue for seven days after the completion of oral chemotherapy (Griffin, 2003). Patients should be taught to return unused oral chemotherapy medications to the pharmacy or clinic for proper disposal. Patient should be advised not to throw oral chemotherapy medications in the trash or flush them down a toilet, so as not to contaminate the public water supply and landfills (Bartel, 2007; Moore, 2007). Patients should wash their hands immediately after touching oral chemotherapy medications, and people other than the patients should not handle them at all. If caregivers must handle oral chemotherapy medications, they should wear gloves or pour the proper amount of oral chemotherapy medication into a paper cup and hand it to the patient. Any gloves, paper cups, oral syringes, spoons, or other objects that come into contact with oral chemotherapy medications should be put into a resealable bag and brought to the clinic for proper disposal (Bartel, 2007; Moore, 2007). Other safety measures that should be discussed with the patients are as follows.

- Take oral chemotherapy medications around the same time each day.
- Do not make up missed doses, but make a note of them on the calendar.
- Do not share medications with anyone.
- Store medications in a safe place so that pets, children, and other people are less likely to touch them.

**The Importance of Adherence**

Adherence is important to obtain the best therapeutic response. According to Birner (2003), if patients do not take their oral chemotherapy medications as prescribed, do not avoid medications and foods that interact with them, or do not report symptoms such as frequent diarrhea and vomiting, the chances of therapeutic failure are high. Oral chemotherapy must be present in systemic circulation in its active form to have efficacy approaching or equal to that of IV chemotherapy. To break down into a form the body can appropriately absorb, the medication must spend time in various portions of the gastrointestinal tract. If an oral chemotherapy medication is unable to spend the appropriate amount of time in the

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**Figure 2. Example of a Medication Calendar**

(Continued on next page)
gas
trointestinal tract, then the efficacy of the medication will
be altered. Certain medications or physiologic conditions such
as severe diarrhea alter normal motility and can indirectly af-
flect the breakdown of drugs by altering transit time through
the gastrointestinal tract, which then changes the efficacy
of the medication. Patients must be made aware of the im-
portance of taking oral chemotherapy medications and must
understand that they are at risk for therapeutic failure if the
medications are not taken as prescribed or side effects are not
reported in a timely manner. Patients who understand the se-
riousness of their disease and the fact that adhering to the oral
chemotherapy regimen may control or even cure their cancer
will be more likely to adhere to oral chemotherapy treatment
(Moore, 2007).

**Insurance**

The cost of oral chemotherapy can be a financial burden, and
ability to pay may impede adherence. Verification of insurance
coverage and use of financial assistance are very important. Most
specialty pharmacies have support staff available to verify insur-
ance, notify the office when prior authorization is needed, and
find financial assistance or copay assistance for patients in need.
Just like IV chemotherapy, oral chemotherapy is expensive.
Cassidy et al. (2006) compared the total cost of treatment for
two oral and two IV colorectal cancer treatment regimens with
similar clinical profiles. Although the oral chemotherapy medica-
tions were more expensive than the IV chemotherapy medica-
tions, the money saved on administration charges and treatment
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of adverse events made the oral regimen less expensive overall. The costs associated with a 28-day regimen of oral chemotherapy compared to IV chemotherapy for colorectal cancer are almost identical when you take into consideration the costs associated with IV administration, pump rental fees for continuous infusions, and IV disposable expenses (Moore, 2007).

Even though most insurance companies cover oral chemotherapy medications, sometimes the copays make the drugs unobtainable. For such situations, various copay and financial assistance programs are available to help patients afford oral chemotherapy. Wilkinson (2003) outlined financial aid available through patient assistance programs and pharmaceutical companies. In addition, www.needymeds.com is an excellent resource to locate financial assistance. For patients who are insured through Medicare, Part B does not cover oral chemotherapy unless the oral chemotherapy medication is also available in IV form. Healthcare professionals may have to remind pharmacy personnel to file claims first with Medicare B and then file the remainder of the balance with the patient’s secondary insurance as long as it is not a Part D plan. Medicare will not pay for an oral medication under both part B and D plans. Patients who have Medicare are subject to what is called the doughnut hole, which basically means a gap in coverage where they have to pay full price for the oral chemotherapy medication for a period of time each year. Bartel (2007) provided an excellent overview of Medicare and the doughnut hole. Insurance is a complex issue; representatives in specialty pharmacies may be best equipped to handle the insurance process because they deal with it on a daily basis and have learned to understand the complex issues related to insurance verification and approval for oral chemotherapy.

Conclusion

The oral chemotherapy nursing role was initiated in August 2008. Since that time, she has cared for as many as 112 patients at one time. Initial teaching was provided for 163 patients. Nursing assessment and interventions were provided for 1,710 patient visits prior to the start of the next cycle of chemotherapy (includes patients being seen multiple times). Telephone triage was provided for 2,410 patient calls. Time spent refilling prescriptions has not been evaluated. Since August 2008, three patients have altered from their prescribed doses of oral chemotherapy during one cycle. Of those three cases, two were taught while the oral chemotherapy nurse was on vacation. With a nurse following patients taking oral chemotherapy, patient safety has improved because patients understand how and when to take their chemotherapy medications, when to report side effects, and comply with appointments and medication. Patient documentation of side effects also has improved.

Many complex issues have been raised with the increased use of oral chemotherapy medications. We have only scratched the surface of this new paradigm in the treatment of cancer. The use of oral chemotherapy is expected to rise. As nurses, we must do our part to make sure that patients who take oral chemotherapy are safe. To do so, we must advocate for dedicated nurses (or other, equivalent models) to care for patients receiving oral chemotherapy in our practice settings.

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