Current Practice Patterns for Oral Chemotherapy: 
Results of a National Survey

Janna C. Roop, RN, PhD, CHPN, and Horng-Shiuann Wu, RN, PhD

The administration of chemotherapy drugs has shifted dramatically in the past 15 years from parenteral to oral administration (Moody & Jackowski, 2010). Along with this change has come increased responsibility for patient self-management. With oral chemotherapy, patients and their families bear the burden for the five rights of medication administration: right patient, right drug, right dose, right time, and right route. In addition, patients must understand administration directions, properly store and dispose of medications, recognize adverse effects as being related to their chemotherapy, and report those effects to the appropriate care provider.

A substantial body of literature indicates that patient and family education and follow-up are critical to treatment success with oral chemotherapy (Bedell, Hartigan, Wilkinson, & Halpern, 2002; Birner, Bedell, Avery, & Ernstoff, 2006; Chau, Legge, & Fumoleau, 2004; Gerbrecht & Kangas, 2004; Hartigan, 2003; Moody & Jackowski, 2010; Moore, 2007; Smith & Carter, 2010; Szetela & Gibson, 2007; Weingart et al., 2011, 2012; Weingart, Mattsson, Zhu, Shulman, & Hassett, 2012). Suggested strategies include specialized prescription instructions, medication diaries, dose monitoring (Khandelwal, Duncan, Ahmed, Rubinstein, & Pegus, 2011), monitoring and reinforcing teaching at each office visit, and follow-up telephone calls (Staddon, 2011). To date, however, national data about the actual practices related to oral chemotherapy treatment are not available, particularly in the outpatient setting where most oral chemotherapeutic agents are prescribed and managed. Oncology nurses often are at the front line of providing care for patients treated with oral chemotherapy (Winkeljohn, 2007). Nurses, therefore, have insight into the most difficult problems those patients face, and may be able to collaborate with their interdisciplinary colleagues to improve the standard of care, if necessary.

Purpose/Objectives: To describe current nursing practices in the United States regarding care and safety of patients taking oral chemotherapy.

Design: This three-phase study consisted of development, validation, and implementation of a national online survey.

Setting: Survey of oncology nurses in outpatient settings.

Sample: 577 oncology nurses.

Methods: Surveys were emailed to 5,000 members of the Oncology Nursing Society. The survey included 17 forced-choice items and one free-text item. Descriptive statistics and content analysis were obtained.

Main Research Variables: Patient care practices, nursing resources, and barriers to medication adherence.

Findings: Fifty-one percent of the respondents worked in practices that had developed specific policies, procedures, and resources for patients on oral chemotherapy. Barriers to treatment adherence included cost (81%) and adverse effects (72%). Practices with specific policies differed in clinical and statistical significance from practices without policies on almost every survey item. Free-text responses revealed that many practices have erratic procedures and inadequate interdisciplinary communication.

Conclusions: Systematic reliable policies and procedures for patient education, documentation, and interdisciplinary communication are urgently needed.

Implications for Nursing: Nurses should provide education and repeated teaching to improve patient safety, adherence to the medication, and self-monitoring for adverse effects.

Key Words: ambulatory care; oral chemotherapy; chemotherapy; clinical practice; patient education

The purpose of the study was to explore and describe current nursing practices in the United States regarding care and safety of patients who are taking oral chemotherapy. The study had two specific aims: (a) to uncover nurse perspectives relative to the challenges in current practices for oral chemotherapy treatment and (b) to identify common barriers to treatment adherence among patients receiving oral chemotherapy.
Methods

This study consisted of three phases. In phase 1, the investigators collected data about the issues and challenges in patient care faced by oncology nurses to generate an item pool for an electronic survey. In phase 2, the investigators created the survey and evaluated its content validity. In phase 3, the investigators administered the survey, via email, to a national sample of oncology nurses. Each phase was approved by the institutional review board at Wayne State University.

Phase 1: Preliminary Study

Preliminary data for the study were collected in 2009 from the Nurse Network Retreat of the Michigan Society of Hematology and Oncology, a statewide annual conference for oncology nurses. During lunch, volunteers led informal table conversations about issues regarding patients taking oral chemotherapy. Conversations were not recorded, but discussion leaders took notes that were transcribed to create text. After lunch, the primary investigator led a whole-group session where nurses responded to 19 researcher-created statements using an audience response system (clickers) (see Figures 1 and 2). Responses were collated and descriptive statistics obtained. A few weeks later, focus groups were held for two groups of nurses (n = 6 and 3) working in local private physician offices. The focus groups were recorded and transcribed to create a text for analysis.

Sample: The sample for this phase, including conference attendees and participants in the focus groups, consisted of 53 Caucasian nurses, 74% of whom worked full-time. Their average age was 48.1 years (SD = 9.3), 38% held an associate degree in nursing, and 43% held baccalaureate degrees. On average, they had worked in oncology settings for 15 years (SD = 8.5).

Results: Sixty-seven percent of the nurses attending the conference reported that policies and procedures for oral chemotherapy had not been developed at their practice settings. It was difficult to know which patients were taking oral chemotherapy, and no systems were in place for assessing adherence. The nurses also reported that they had inadequate time for patient and family teaching, and they were uncertain if their patients would notify anyone if they decided to stop taking their medication.

The nurses in the focus groups reported that the medications could be prohibitively expensive, often costing thousands of dollars per month. Financial assistance was available, but applying for that assistance was described as “like applying for a college scholarship” or “applying for a mortgage,” requiring several hours of nurse time . . . that was not reimbursable. It was not uncommon for patients to wait one or two months before receiving their medication.

The nurses in the focus groups also reported that no reliable systems were in place for keeping track of patients who were prescribed oral chemotherapy. The medications have differing onsets of therapeutic or adverse effects, but when patients called in with questions, it was easy for the nurse to mistake the date of the prescription for the date of the first dose, forgetting that there often was a lag time of up to several weeks between the writing of the prescription and the arrival of the medication.

Phase 2: Development and Content Validation of the Survey

In this phase, the 19 statements used for the conference session went through three sequential revisions by three different panels of experts. The first panel included three nurses with graduate degrees who had expertise in research methods and/or oncology. The second panel consisted of two oncology nurses who provided direct outpatient care, and the third panel consisted of four oncology nurses with advanced degrees. The content experts reviewed each of the survey items by rating each item for representativeness and...
relevance on a four-point rating scale ranging from 1 (the statement is not representative of current nursing practice for patients taking oral oncologic medications) to 4 (the statement is representative of current nursing practice for patients taking oral oncologic medications). Each panel identified unclear items, suggested additions or deletions, and commented on the questionnaire as a whole.

After each review by a panel, kappa coefficients were obtained, and each time they ranged from 0.33 (fair agreement) to 1 (perfect agreement). Using the kappa coefficients and responses from the expert reviewers, the investigators revised the survey before submitting it to the next panel. The final survey consisted of 26 items: one to acknowledge consent, seven to establish demographic data, and 17 that addressed three content areas, including practice setting, resources available for nurses, and common barriers to patient adherence to medication regimens. A five-point Likert-type scale ranging from 1 (strongly agree) to 5 (strongly disagree), with an additional choice of “I don’t know,” was used for the 17 content items. A final free-text item provided space for participants to enter comments.

Phase 3: National Online Survey

In phase 3, the investigators distributed the survey to a national sample of oncology nurses (see Figure 3). The refined instrument was entered into an online survey program (SurveyMonkey®) and emailed to a random anonymous sample of 5,000 members of the Oncology Nursing Society (ONS) who worked in outpatient settings in the United States. Two weeks after the initial email, a reminder was sent by follow-up email to all 5,000 nurses. The survey was open for 10 weeks, from April to June 2012.

Sample: A total of 656 responses were received, for a response rate of 13%. Nine respondents were excluded from the study because they did not give consent. The remaining sample of 647 was overwhelmingly female (96%), Caucasian (91%), worked full-time (75%) in outpatient settings (85%), and had more than 15 years of experience in oncology nursing (52%). In addition, the majority of the respondents had a bachelor’s degree in nursing (42%), and 85% of all respondents had provided nursing care to patients treated with oral chemotherapy in the prior six months (see Table 1). After demographics were analyzed, 70 respondents were excluded from further analysis because either they had practiced oncology nursing for less than one year (n = 1), or they had not cared for patients taking oral chemotherapy in the past six months (n = 69). The final sample of 577 oncology nurses was used for the remaining analysis.

Results: For the analysis of survey data, the categories “strongly agree” and “agree” were collapsed into one category, as were the categories “strongly disagree” and “disagree.” Descriptive statistics were then obtained from the 17 content items. Results are presented in Figures 4 and 5.

Practice settings: Although specific policies, procedures, and guidelines for managing patients undergoing oral chemotherapy were available in 51% the practice settings, just under half of the nurses (47%) reported that there were no policies or procedures for documenting patient adherence to the medication regimen. Resources were available for patients undergoing oral chemotherapy, including adequate patient...
1. My practice has policies, procedures, and/or guidelines that are specifically for patients taking oral chemotherapy medications.

2. My practice has policies, procedures, and/or guidelines for documenting compliance with the medication regimen for patients taking oral chemotherapy medications (e.g., pill counts, pill diary, patient self-report).

3. My practice has policies, procedures, and/or guidelines to manage patients who experience adverse reactions to oral chemotherapy medications.

4. My practice has adequate educational materials for patients taking oral chemotherapy and their families (pamphlets, information sheets, videos, hotline for questions).

5. My practice maintains a list of pharmacies that can fill prescriptions for oral chemotherapy medications.

6. My practice maintains a list of resources to assist patients with the cost of oral chemotherapy medications.

7. If a patient stops taking his or her oral chemotherapy medications, he or she will notify my practice.

8. In my practice, when a patient receives a prescription for an oral chemotherapy medication, there is a system for notifying nurses about that prescription (e.g., flag chart, keep names on a list, documentation in the medication reconciliation record).

9. 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).

10. Nurses in my practice have adequate educational resources regarding oral chemotherapy medications.

11. I have enough knowledge about oral chemotherapy medications to provide safe care for patients.

12. When a patient is prescribed an oral chemotherapy medication, there is sufficient time for the nurse to teach the patient and family about the medication (dosing, storage, precautions, management of side effects, disposal of medications).

13. When a patient is prescribed an oral chemotherapy medication, there is sufficient time to teach the patient and family about the “red flags” or danger signs and symptoms that should be reported to the providers right away.

14. When a patient is prescribed an oral chemotherapy medication, there is sufficient time for follow-up and/or reinforcement of the original teaching about the medication.

15. One of the largest barriers to patient compliance with oral chemotherapy medication is side effects from the medication.

16. One of the largest barriers to patient compliance with oral chemotherapy medication is the cost of the medication.

17. One of the largest barriers to patient compliance with oral chemotherapy medication is the complex instructions about taking the medication.

18. Please use the space below to list any comments, questions, or observations about caring for patients taking chemotherapy medications or this survey.

Note. For all statements, participants used a five-point Likert-type scale (strongly agree, agree, neither agree nor disagree, disagree, strongly disagree) with an additional option (I don’t know).

Note. The original questions 1–8 collected content and demographic data and were not included in this figure.

Figure 3. Items for the Online Survey
Sometimes the first opportunity that nurses would learn that a patient had been prescribed an oral drug was when the patient would call the triage nurse with a problem. One respondent noted, “We have a nurse that makes weekly phone calls to check on compliance and see if our patients are having problems, but I do not know who she communicates the information with as I do not talk with her. She only comes in one day a week, and it’s after hours.” One respondent said that, although the doctors usually asked her to do teaching, the number of patients in the practice was too great for her to provide adequate individualized teaching and follow-up. The result, she said, was that she was often responding to problems rather than performing the teaching that could prevent some of those problems.

An unexpected finding was that, in some cases, use of an electronic medical record (EMR) was actually a hindrance to efficient communication. Typical comments included, “Because of EMRs, it is difficult to find a way to flag a chart or keep a side effect check sheet handy,” and “We have implemented new computer software . . . but it does not interface with the original charting system.”

**Delays and expense:** Like the nurses in phase 1, survey respondents decried the delays and expense associated with oral chemotherapy. They reported complex and time-consuming procedures for acquiring the drugs and the prohibitive expense of the drugs. One respondent noted, “[The requirements to procure drugs are] confusing to even the insurance people when patients call, and can really cause problems for them when ordering, increasing frustration and anxiety.” Even if financial assistance could be obtained, the process sometimes led to delays of a month or more before patients could receive the drug. If patient teaching occurred at the time the drug was prescribed, many patients had forgotten key points by the time the drug arrived. It was particularly difficult, then, to assess who needed to be re-educated and, if so, of what content. Particularly troubling were the older adult patients who had to choose between using life savings to obtain the best drug for their cancer and protecting those savings, especially if a surviving spouse would be dependent on those savings. As one respondent said, “Dealing with a diagnosis of cancer is difficult enough; patients shouldn’t have to face this type of financial conflict.”

**Education and resources:** Many respondents noted that, not only did patients require more education, but the nurses and their nursing colleagues were inadequately prepared regarding oral chemotherapy. One nurse educator observed, “I find that I do not have adequate access to [information about] the new drugs coming out or adequate education for myself. The outpatient clinics are losing touch with the pharmacuetical companies because of restrictions applied to what they can bring and how often. In the past, this was our connecting arm to the pharmacy world.”

**Nursing time:** One of the most common concerns was the amount of time it takes for nurses to properly care for patients taking oral chemotherapy. As noted in the previous section, the drug regimens are complicated and patients often need to be taught the same information more than once. One respondent stated, “Oral medications take longer to explain and monitor because patients are in their own environment. Extra steps must be taken (e.g., patient diaries, extra telephone calls).” Adding to the time burden were the cumbersome procedures necessary to procure payment or financial assistance to obtain the drugs.

### Table 1. Sample Demographics (N = 647)

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<tr>
<th>Characteristic</th>
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<td>2</td>
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<td>1–10</td>
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*Note. Because of rounding, not all percentages total 100.*
Even if sufficient time did exist, results were not always as expected. One clinical nurse specialist said, “I have the time to teach, but...it seems no matter how much information I give in a variety of formats, patients are human, and they forget to follow the specific instructions. This occurs even when this is all written out for an English-speaking, literate patient. Sometimes I feel like I am banging my head against the wall.”

**Patient barriers:** As could be expected, many respondents identified patient barriers to successful treatment. As one respondent noted, all of the barriers to adherence to other medications are present for patients taking oral chemotherapy: “I only take the medicine with food, and I wasn’t hungry this morning,” “I forgot to take it at night,” or “The pills are too big. I can’t swallow them.” Many patients erroneously believe that oral medications are neither as strong nor as toxic as IV medications, so they may not appreciate the seriousness of taking the medication correctly. Patients on long-term therapy may just tire of the adverse effects. When adverse effects occur, many patients do not call because they do not want to “bother” the providers. Some patients do not report adverse effects because they believe they should “tough it out,” or they fear their cancer more than they fear the adverse effects. Some patients will stop taking the medications because of adverse effects, but neglect to notify the provider for weeks in some cases. This decision can literally cost them their lives.

One respondent asserted that patients should be screened for their ability to adhere to oral chemotherapy. Patients with cognitive deficits or who are functionally...
illiterate may not be appropriate candidates for this therapy because of their limitations in understanding complex written instructions.  

Potential solutions: Although the survey revealed serious concerns about the safety of oral chemotherapy, many respondents reported that they had begun taking steps to address the problems and offered suggestions for improvement of care. Respondents reported moderate success with common organizational tools such as prefilled medication boxes, patient diaries, and calendars that clearly indicated medication schedules, blood work appointments, and follow-up appointments. Other strategies included

- Maintaining a weekly call list for each patient on oral chemotherapy
- Developing standardized documentation forms for telephone calls that include administration instructions, precautions, monitoring of adverse effects, and so on
- Scheduling patients for two education appointments prior to prescribing oral chemotherapy
- Scheduling routine follow-up phone calls 48 hours after the beginning of the chemotherapy or scheduling one week follow-up office visits
- Providing classes for nurses and adding oral chemotherapy as an annual competency

Several respondents reported that their practice had a nurse, either full- or part-time, who was dedicated only to patients on oral chemotherapy and, in some settings, that nurse was bilingual (English and Spanish). Others reported that an oral chemotherapy prescription automatically triggered an education appointment with a nurse or pharmacist. Some practices had an oral chemotherapy coordinator who would help patients navigate the process of obtaining and paying for the drug. Respondents reported their belief that safety was enhanced when patients could obtain their drug from a dedicated pharmacy, either on-site or at a specific specialty pharmacy, but insurance companies did not always allow this. When communication was well coordinated, respondents found it very helpful to collaborate with pharmacists for patient education and follow-up, as long as redundancy was avoided.

Discussion

Oral chemotherapy is a relatively new treatment option, so the fact that some practices are struggling to develop systems for managing this treatment is not surprising. Quantitative data revealed that 51% of the surveyed practices have already developed policies, procedures, and resources to meet the new treatment paradigm. Still, that means that about half of the respondents work in practices that do not have a coordinated system for caring for those patients. Also, as could be expected, the investigators found differences in nursing practice patterns depending on whether specific policies, procedures, and guidelines were in place for oral chemotherapy. Respondents who worked without specific guidelines differed significantly on almost every item from those who worked with guidelines (p = 0.047 or less). For example, they reported less confidence in their ability to provide safe care because of their own knowledge deficits. They also reported fewer resources for nurses and patients, and less guidance for management of adverse reactions. In the free-text comments, respondents identified problems with interdisciplinary communication and continuity of care, delays and expenses related to the medications, patient barriers, time pressures on working nurses, and nurse access to timely education and resources.

Results of the current study are consistent with Weingart et al. ’s (2007) findings that oral chemotherapy raises safety concerns. In their study of National Cancer Institute-designated cancer centers, Weingart et al. (2007) found that responsibility for patient education was shared among physicians, nurse practitioners, nurses, and pharmacists; however, two-thirds of the centers did not verify the qualifications of the personnel providing the education. In addition, many of the safeguards in place for IV chemotherapy prescriptions (e.g., double-checking with another provider, calculating body surface) were not required for oral chemotherapy, and few other coordinated protocols were in place.

The American Society of Clinical Oncology and ONS have published and updated standards for chemotherapy administration safety (Neuss et al., 2013). The 2013 standards were expanded to include oral chemotherapy. All editions of the standards assert that patients and families must receive extensive education about their chemotherapy before treatment begins. In the current study, however, the investigators found that a substantial number of respondents (23%) reported that they do not have the time for such careful education.
Moody and Jackowski (2010) described how one cancer treatment facility responded to the challenges of patient adherence to oral chemotherapy by creating the role of oral chemotherapy nurse. The nurse was responsible for identifying those patients taking oral chemotherapy, providing specific patient-centered education about their drugs, and monitoring patient progress. In the two years following creation of the nurse role, only 3 of 1,710 patients were known to have varied from their prescribed regimens, suggesting that the oral chemotherapy nurse obtained excellent adherence outcomes. In the current survey, the free-text responses indicated that some practices had created a position for an oral chemotherapy nurse—a promising trend.

The Institute of Medicine reported that 44,000–98,000 deaths per year in the United States could be attributed to medical errors (Kohn, Corrigan, & Donaldson, 2000). A decade later, Clancy (2009) reported that progress toward reducing medical errors has been frustratingly slow. Among her suggested strategies for reducing errors is improving interdisciplinary communication and teamwork. That suggestion is particularly pertinent for the current study because many respondents reported inadequate communication between the medication prescribers and the nurses who perform the patient teaching. In many practice settings, interdisciplinary communication and teamwork were inadequate.
Limitations

To the investigators’ knowledge, this study is the first in the United States to investigate nurse assessments of their own practice related to oral chemotherapy. A rigorous process was used to develop the survey questions. The validity of the survey was further supported by respondent comments, such as “All of the concerns that you have identified in this survey do present real challenges for providing the necessary care.”

Although this study recruited a national random sample of oncology nurses, several limitations could reduce generalizability. First, the survey had a low response rate (13%). Whether nonrespondents differed in important ways from respondents is unknown. Second, the study participants consisted mainly of experienced nurses with many years of oncology practice (86% had 10 or more years); therefore, nurses newer in the field are under-represented. The lack of racial, gender, and experience diversity among the respondents also may have biased the findings, and because no personal identifiers were collected, whether the observed practice patterns varied by region is unknown. Finally, the survey used a five-point Likert-type scale with an additional option of “I don’t know.” For data analysis, however, data were collapsed to “agree” and “disagree.” Although this facilitated interpretation of the dichotomous responses, it also precluded analysis of the strength of agreement or disagreement. In addition, all of the responses of “neither agree nor disagree” were excluded from the analysis. Study findings should be interpreted cautiously, particularly the results of the three items where 22%–28% of respondents chose the neutral midpoint.

• If a patient stops taking his or her oral chemotherapy medications, he or she will notify my practice.
• When a patient is prescribed an oral chemotherapy medication, there is sufficient time for the nurse to teach the patient and family about the medication (dosing, storage, precautions, management of side effects, and disposal of medications).
• One of the largest barriers to patient compliance with oral chemotherapy medication is the complex instructions about taking the medication.

Implications for Research and Practice

Medical errors that include medication errors are still far too common in the United States. Oral chemotherapy has a high risk for serious errors because of the narrow therapeutic ranges, high potential for toxicity, and the transfer of responsibility from healthcare professionals to patients and their families. All prescribing practices should develop policies and procedures to ensure effective interdisciplinary communication to safeguard patients. Nurses caring for patients who take oral chemotherapy should become familiar with the Oral Adherence Toolkit available on the ONS website (http://bit.ly/1bUDgHf). Preventive strategies also should be employed, such as having a dedicated oral oncology nurse and providing time for patient and family education. Additional research is needed to determine what patients actually learn about their medications and how they apply that learning, how to screen for patients who cannot safely manage their own medications, how to determine the best practices in patient education and monitoring, and how to develop and test various teaching methods. Rigorous reporting of errors also will provide evidence about the safety of those drugs.

Conclusion

In spite of the risks and challenges associated with oral chemotherapy drugs, their use is likely to become more prevalent. In 2012, about 10% of all chemotherapy was given in oral form, and the use is expected to increase (Charpentier, Orr, & Taveira, 2012; Yagasaki & Komatsu, 2013). In addition, many patients prefer oral drugs over parenteral ones, even if they erroneously believe that the oral drugs are less effective (Findlay, von Minckwitz, & Wardley, 2008; Palmieri & Barton, 2007). They prefer the convenience of staying at home and the flexible timing that oral drugs offer, as well as the comfort of avoiding needles (Aisner, 2007; Liu, Franssen, Fitch, & Warner, 1997). Unless patient safety and adherence can be ensured for the new and promising medications, however, their efficacy and safety may be severely compromised. As C. Everett Koop observed, “Drugs don’t work in patients who don’t take them” (Osterberg & Blaschke, 2005, p. 487). The investigators would add that this also holds true for those who take them incorrectly.

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