Impact of Oral Anticancer Medication From a Family Caregiver Perspective

Victoria K. Marshall, PhD, RN, Eric A. Vachon, BSN, RN, Barbara A. Given, PhD, RN, FAAN, and Rebecca H. Lehto, PhD, RN

Oral anticancer medication (OAM) use has become common in oncology treatment as more oral agents are approved for managing various types of cancer (Verbrugghe, Verhaeghe, Lauwaert, Beeckman, & Van Hecke, 2013). More than half of all newly prescribed cancer treatments approved by the U.S. Food and Drug Administration are currently in oral form (Center Watch, 2018). OAM administration is convenient, but patients and their caregivers are required to self-manage cancer care in the home environment without the strict supervision of oncology professionals (Given, Spoelstra, & Grant, 2011). Family caregivers of patients receiving OAM may face specific treatment challenges that interfere with their ability to support patients, including cost, adverse events, toxicities, limited access to health care or pharmacy services, complex dosing regimens, and lack of caregiver social support (Given et al., 2011; Neuss et al., 2013; Spoelstra et al., 2013). Although studies have shown that caregivers often need social support and other resources to care for patients with cancer (Northouse, Katapodi, Song, Zhang, & Mood, 2010), little is known about the impact of OAM on family caregivers, their ability to cope with responsibilities of treatment management in the home environment, and their needs for supportive resources. In addition, research is limited regarding how caregiving for family members receiving OAM differs from those receiving more commonly delivered IV chemotherapy. The purpose of the current focus group study was to evaluate family caregiver perceptions about challenges and resource needs associated with providing care for patients receiving OAM in the home environment.

PURPOSE: To describe how family caregivers of patients receiving oral anticancer medication (OAM) may affect family caregivers’ lives and determine what support caregivers need to manage OAM in the home successfully.

PARTICIPANTS & SETTING: Family caregivers of individuals with cancer prescribed OAM recruited from oncology clinics in the Midwest region of the United States.

METHODOLOGIC APPROACH: Focus group methodology was used to elicit caregivers’ perspectives. Sessions were audio recorded and transcribed verbatim. Qualitative analysis used a constant comparative approach.

FINDINGS: Themes specific to OAM treatment were convenience, safe handling, financial worries, and medical impact of OAM treatment course.

IMPLICATIONS FOR NURSING: Providing support and educating caregivers on preparation, administration and safe handling, precautions for the handling of patient bodily fluids, potential for treatment interruptions, and financial assistance and resources for OAM may bolster effective caregiving in home environments.

KEYWORDS cancer caregivers; cancer; oral anticancer medications

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antineoplastic, anticancer agent, oral agent, and oral chemotherapy. Literature involving caregivers of patients receiving OAM published from 2001–2017 in English were included. The U.S. Food and Drug Administration began approving OAMs in 2001 (American Society of Clinical Oncology, 2017) and is the rationale for including literature published within this timeframe.

OAM offers a convenient alternative to IV chemotherapy by allowing patients to receive their treatment in the home environment (Barni et al., 2016). Traditional forms of cancer therapy and OAM share many of the same burdens of treatment for patients and their family caregivers, such as physical, emotional, coping, and financial demands (Sercekus, Besen, Gunusen, & Edeer, 2014). However, there are distinct challenges with OAM (Siden et al., 2014). Issues associated with OAM treatment include concern for the mental ability of the patient to remember and correctly follow the OAM regimen (Lonardi, Bortolami, Stefani, & Monfardini, 2007) and the physical capability to self-administer the OAM treatment in the home environment (e.g., the ability to swallow pills or capsules) (Lonardi et al., 2007; Siden et al., 2014). There is also an increased need for caregiver oversight to ensure oral adherence (Lonardi et al., 2007; Weingart et al., 2008) and self-manage symptoms and adverse events of the OAM without the continuous monitoring of oncology professionals (Lonardi et al., 2007; Weingart et al., 2008). In addition, safety surrounding the handling, preparation, administration, storage, and disposal of OAM (Siden et al., 2014) or accidental exposure of OAM to oneself or others in the home (Weingart et al., 2008) is a concern for patients and caregivers. Cost of the medication (Lonardi et al., 2007; Weingart et al., 2008) and concerns regarding obtaining OAM from specialty pharmacies are also challenges facing patients and their caregivers (Simchowitz et al., 2010; Weingart et al., 2008).

Patients and caregivers need adequate education to prepare them to handle the challenges of administering OAM in the home (Simchowitz et al., 2010). Patients and caregivers may have access to oncology professionals to answer questions and address concerns but could require additional oncology professional-initiated follow-up to ensure there are no issues regarding oncology care in the home (Simchowitz et al., 2010). In addition to oncologists and nurses, who offer a majority of the initial education to patients and their family caregivers, pharmacists are also pivotal in offering OAM education (Avery & Williams, 2015; Lester, 2012; MacLeod et al., 2007; Simchowitz et al., 2010). Specialty pharmacies are noted to be better equipped to offer patient education compared to community retail pharmacies because of their increased training in oncology treatments (Abbott, Edwards, Whelan, Edwards, & Dranitsaris, 2014; Weingart et al., 2008). However, pharmacists located within specialty pharmacies may be met with barriers to provide individualized education because of inadequate access to patient medical records and lack of communication with oncology professionals (Wong, Bounthavong, Nguyen, Bechtoldt, & Hernandez, 2014).

Several guidelines and educational materials regarding OAM are available from professional oncology organizations, such as the American Society of Clinical Oncology (ASCO), Oncology Nursing Society (ONS), and the National Comprehensive Cancer Network (Neuss et al., 2016; Weingart et al., 2008). Safety standards set forth by ASCO and ONS indicate that patients and caregivers should be provided with verbal and either written or electronic materials during education before the initiation of treatment (Neuss et al., 2016). Such education includes financial resources; safe handling, preparation, administration, storage, and disposal of OAM in the home; procedures for handling bodily secretions and/or wastes; use of proper hazardous warning labels of chemotherapy medication; and symptoms or adverse events to expect and report to oncology professionals (Lester 2012; Neuss et al., 2016). ONS also provides instructional videos highlighting care with OAM medication that patients and caregivers can refer to (ONS, n.d.). However, some patients and caregivers may fail to receive sufficient information regarding OAM despite these safety standards, and steps must be taken to ensure proper and timely education, particularly when cancer care is managed in the home environment (Spoelstra, 2015).

Interventions to support patients receiving OAM often do not include caregivers and are limited to studies involving oral capecitabine for colon cancer (Craven, Hughes, Burton, Saunders, & Molassiotis, 2013; Dalby et al., 2013; MacLeod et al., 2007), with some exceptions (Kondo et al., 2015). In addition, interventions most often involve monitoring of toxicities and adverse events (Craven et al., 2013; Kondo et al., 2015) and do not address other challenges associated with OAM, which can cause caregiver needs to remain unmet (Ream et al., 2013). Interventions, such as OAM clinics, can provide education, a review of drug interactions, and a review of symptoms and
side effects (Wong et al., 2014). Safe handling of OAM is a safety concern for patients and their caregivers, and studies have noted that safety precautions are not always followed according to outlined recommendations (Trovato & Tuttle, 2014).

Caregivers of patients receiving OAM face new challenges associated with cancer care. Limited studies identify the needs of these informal caregivers and involve caregivers in interventions for this population (Ream et al., 2013). Caregivers can have unmet needs that negatively affect patient care (Ream et al., 2013). In addition, caregivers of patients receiving OAM may require more frequent follow-up initiated by oncology professionals to assess needs and provide additional education and support (Ream et al., 2013). Challenges surrounding caring for patients with cancer receiving OAMs in the home environment raises questions regarding how individuals are screened as appropriate candidates for OAMs, including proper social support and caregiving in the home.

Purpose
This article presents two aims of a more comprehensive focus group study using an inductive approach that involves the perspectives of family caregivers of patients receiving OAM that addresses adherence, self-management of symptoms, and adverse events. The study purpose is to examine the specific challenges that affect the lives of family caregivers of patients receiving OAM in the home environment. A second purpose is to determine what support is needed to effectively manage care in the home environment. Results of the focus groups can be used to potentiate the formulation of future conceptual or theoretical knowledge to better the understanding of issues facing family caregivers of patients receiving OAMs. The new findings will enhance knowledge that will inform future research and practice application.

Methods
Setting and Participants
The study was reviewed and approved by the Michigan State University Institutional Review Board in East Lansing. Participants from one free-standing and two hospital-based oncology clinics in the Midwest region of the United States were recruited if they met the following inclusion criteria: (a) family caregivers of patients with cancer who were prescribed OAM; (b) English speaking; (c) aged 21 years or older; and (d) able to hear, verbally communicate, and comprehend the nature of the study.

Procedure
Participants meeting the inclusion criteria were identified by oncology site recruiters and were asked permission to be contacted by researchers. Those who agreed to participate gave verbal consent via telephone. An information packet, which included a written consent document, was mailed to their home or sent electronically via email, depending on personal preference. Focus group questions were developed to correspond with study aims and were reviewed by a panel of senior researchers specializing in cancer caregivers and OAM. A list of questions and topics were provided in advance to familiarize the participants with focus group content. Two focus groups were held by researchers in hospital conference rooms affiliated with the oncology clinics, each lasting about 80–90 minutes. The first focus group included three participants, and the second focus group included four participants. To ensure participants felt free to share their experiences, no clinical oncology staff were present. All focus group sessions were audio recorded. Examples of focus group questions regarding impact on caregivers’ lives include the following:

- How has your family member’s oral anticancer treatment affected you?
- What was the hardest thing about managing the OAM regimen?
- What was the easiest thing about managing the OAM regimen?
- Did you feel prepared to help your loved one manage his or her OAMs at home?

To ensure credibility, participants were asked to clarify their responses if they were unclear to the researchers. Family caregivers confirmed the moderator’s interpretations of responses as needed and at the conclusion of each session. Confirmability was established at the conclusion of focus groups between the researcher who served as the moderator and the researcher taking field notes. In addition, each researcher’s independent analyses of the data served to confirm results.

Analyses
To ensure rigor in the process, audio recordings were transcribed verbatim. Constant comparative analysis, as outlined by Krueger and Casey (2015), guided the evaluation of data. Constant comparative analysis allowed the study researchers to compare portions of the data from all participants to identify similarities and differences in responses, leading to the discovery of relationship patterns within the data (Krueger &
Two study nurse researchers who guided the focus group sessions and who had expertise in focus group methodology completed independent data analyses. Any discrepancies between researchers’ analyses were discussed until an agreement was reached, using input from a third senior study nurse researcher as needed.

Findings
Caregiver demographic and pertinent patient health-related data (e.g., age; sex; relationship to the patient; type and duration of OAM treatment; concurrent IV chemotherapy, injections, or radiation therapy) are presented in Table 1. All family caregivers were female. Seven major themes were identified, consisting of convenience, safe handling, financial worries, impact on caregiver, coping, medical management of OAM treatment course, and availability of oncology professionals for support. Many of the identified themes could relate to anticancer modalities more generally. However, of the themes identified, several emerged as specific to treatment with OAM and were consistent with the current literature (i.e., convenience, safe handling, financial worries, and medical management of the treatment course). The themes specific to OAM will be discussed in the current article.

Convenience
The convenience of OAM was noted among all study participants as benefiting the patient and family caregiver. Female family caregivers appreciated not having to commute for treatment and the ease associated with self-administration (see Figure 1).

Safe Handling of Oral Anticancer Medication
The topic of safe handling was discussed in both focus groups. Participants described grave concerns regarding direct OAM exposure and unanimously agreed that this was the most difficult challenge. Female family caregivers also expressed fears regarding exposure to the patients’ bodily fluids. One participant reported less sexual activity because of bodily fluid precautions, which negatively affected their intimate relationship. There was evidence of limited education regarding safe handling in the home, disposal of OAMs, and precautions with bodily fluids. Some participants expressed surprise about the need for such precautions, which increased their anxiety about OAM treatment. Despite published guidelines regarding safe handling of OAMs, one caregiver described handling the medication without gloves, using an ice pick to open the capsule, and mixing the capsule contents into applesauce for daily administration. Overall,

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<th>TABLE 1. Caregiver Demographics and Patient Treatment Information</th>
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*Concurrent treatment consisted of IV chemotherapy, injections, or radiation therapy. OAM—oral anticancer medication.*
Because right now we have nothing [not on OAM]. We are living
Well, it’s very expensive. There is an organization that pays for the
We don’t have insurance right now. We’re kind of between a rock
I thought it was easier than having to bring him here and have IVs
[Revlimid®]/lenalidomide] is not covered by insurance. You have
to make the co-pay, and so every month it’s 100 bucks. A hundred
bucks a month is a lot. You have no idea how many out-of-pocket and
out-of-network [expenses] you have already paid."

“Well, it’s very expensive. There is an organization that pays for the
medication if you qualify, so we took out paperwork. They said that
they are out of funds at this organization, and so now we are starting
to have to pay for it. I had the checkbook, and I was ready to write a
check, and they said, ‘Oh, this is so expensive.’ So they said someone
had turned some in that they didn’t finish using, so they actually gave
me a container that was partially used.”

Medical Impact of OAM Treatment Course
“Because right now we have nothing [not on OAM]. We are living
on the cliff right now. We have been taken off all chemo, all steroids.
We just don’t know what’s coming next. Because the chemo has
been working really good, and then they just cut you off. It’s kind
of a scary little feeling there. So now that we don’t have anything,
we’re both like . . . we’re very emotional, very stressed. We’re just
like . . . we feel like a puppet with strings, and they’re controlling your
life.”

OAM—oral anticancer medication

Concern about OAM safe handling and contact with bodily fluids evoked fear, anxiety, and alterations in the spousal relationship.

Financial Worries
Financial concerns affected participants in both focus groups. Financial worries can have an impact on all patients with cancer receiving various therapies and their caregivers. However, there were financial concerns specific to the cost of OAMs. OAMs can cost more than $30,000 per month for some individuals (Weaver, Moore, Shah, & Serlemitsos-Day, 2013) and may be not covered by medical insurance benefits, which is more typical of IV chemotherapies (Weaver et al., 2013). Instead, the high costs of OAMs are included under pharmaceutical benefits in states where parity laws have not yet been passed (Kircher et al., 2016). Parity laws help ensure that OAMs are covered under medical insurance benefits in the same way as IV chemotherapy, which makes oral anticancer treatment more attainable (Kircher et al., 2016). Some patients with cancer receiving OAMs are required to provide high co-payments under their pharmaceutical benefits, which contributes to associated financial strain (Weaver et al., 2013). Many patients receiving outside funding to augment OAM costs despite having healthcare insurance. However, this external funding had time constraints and negatively affected the mental state of caregivers who were already worried about cost after the designated pharmaceutical funding period was scheduled to end. One caregiver stated that she accepted OAM that had been previously prescribed to another patient to reduce cost.

Medical Impact of Oral Anticancer Medication Treatment Course
Female family caregivers experienced interruptions associated with OAM treatment. Interruptions to OAM treatment are a common result of treatment complications, such as medication intolerance and/or toxicities experienced by the patient (Tipton,
Although interruptions were not necessarily because of treatment complications, such as intolerance of associated medication toxicities, they still induced anxiety. Treatment interruptions may also occur in patients who receive IV chemotherapy; however, family caregivers of those receiving OAM are actively involved in supporting medication administration, which may cause additional stress. When OAM treatment was interrupted, female family caregivers felt they had lost the ability to support the patient. For example, one family caregiver described that her spouse had completed initial therapy for multiple myeloma and had responded well to treatment but was not placed on an OAM maintenance dose. The caregiver described the uncertainty about not knowing if the treatment would be resumed to be stress-evoking and emotionally aversive.

The family caregivers relied on the OAM to bolster their perceptions that the cancer was being treated and that they had an active role in ensuring administration of the medication. When medication interruptions occurred, family caregivers felt extremely anxious and expressed loss of their sense of control.

**Discussion**

Although OAMs are convenient, home self-management brings new issues for family caregivers and patients. Caregivers face similar challenges as with other cancer therapies, but they carry added burden and responsibilities associated with safe handling, medication preparation and administration, cost, and treatment interruptions. To handle the challenges of managing OAM in the home environment, family caregivers need initial and ongoing support from oncology professionals in the form of education regarding safe handling of medication and bodily fluids, OAM treatment regimens that may require interruptions to treatment, and financial assistance and referral.

ASCO and ONS have published standards that include the incorporation of education to patients, family, and caregivers regarding safe handling of medication and precautions with bodily fluids or wastes in the home prior to the initiation of treatment (Neuss et al., 2016). In addition, ASCO and ONS standards recommend proper hazardous warning labels on chemotherapy medication that describe proper handling (Neuss et al., 2016). Despite these professional oncology organizations’ standards, this sample of female family caregivers did not perceive they were prepared and had critical concerns about OAM safe handling and untoward contact with bodily fluids. This knowledge deficit could have resulted from lack of appropriate education or their inability to concentrate and process information under duress during the education process. Such concerns underscore the importance of communication and follow-up of teaching relative to the OAM regimen.

Family caregivers carry the financial burden of OAM treatment. Financial concerns are not only limited to the monetary expense, which can be in excess of $30,000 per month (Truven Health Analytics, 2013), but also extend to other supportive medications and out-of-network costs. Those receiving OAM funding receive only temporary relief and experience uncertainty about how long financial assistance will continue. Female family caregivers expressed worry about costly deductibles and/or lack of insurance. Financial concerns may be compounded in spousal caregivers who depend on the patient for financial support (Chen et al., 2014; Kavanaugh, Kramer, Walsh, & Trentham-Dietz, 2015) and who now face economic uncertainty. In this small sample, the financial impact weighed more heavily for younger family caregivers than older caregivers at or after retirement age. Similar financial concerns of younger family cancer caregivers have been reported (Balfe et al., 2016; Kavanaugh et al., 2015). Financial concerns surrounding the OAM may not have the same impact for nonspousal caregivers.

Many female family caregivers discussed feeling anxious when the OAM treatment was interrupted because of worries that the disruption would affect the patient’s cancer progression. These family caregivers placed hopes on the OAM treatment to successfully delay progression or cure the disease. Oncology nurses are in a position to explain that OAM interruptions are routine, so family caregivers are forewarned and understand the rationale for such treatment adjustments.

Family caregivers noted that they were not aware of safe OAM handling or lacked knowledge of proper handling of bodily fluids. Caregivers identified that they had access to oncology professionals and/or pharmacists if needed, but that these resources were not used. Specialty pharmacies may offer additional reinforcement of initial OAM education, such as safe handling before dispensing and shipping the OAM. Using pharmacists to assist oncology professionals to provide additional educational resources and provide follow-up prior to each medication shipment could be helpful for patients and caregivers.

Although symptom management was mentioned as a potential issue for caregivers in the literature...
review, this did not emerge as being different from the issues related to other cancer therapies. Other themes that emerged during the focus group support that family caregivers of patients receiving OAM face many of the same burdens of traditional cancer modalities, but they also face different challenges.

**Strengths and Limitations**

This study is among the first to report on perceptions of family caregivers of patients taking OAM. The small sample of family caregivers were all female spouses, with the exception of one daughter. Implications for the impact of OAM treatment may differ for spousal caregivers compared to adult children who care for their parents, particularly in the financial realm. Patient demographics, such as age and cancer treatment information (e.g., line of therapy, identification of specific concurrent therapy), were not collected. Focus group studies are meant to provide essential information on complex problems from relevant parties. While not generalizable, the findings can be used to better the understanding of the issues facing female spousal caregivers of patients receiving OAMs. Additional focus groups involving family caregivers of patients receiving OAMs are needed to ensure that data saturation is reached. The inclusion of male caregivers and adult children caring for their parents may lend more comprehensive perspectives.

**Implications for Practice and Conclusion**

Oncology nurses are at the forefront to assess and address the needs for family caregivers of patients receiving OAM. Nurses can offer patient and caregiver education regarding proper safe handling, preparation, and administration, as well as precautions regarding safe handling of bodily fluids and wastes in the home. Participants in this study noted concern about exposure to OAM and bodily fluids. One participant expressed the unsafe preparation of opening OAM capsules by using an instrument to puncture the medication and not wearing gloves. The puncturing of capsules can inadvertently lead to unsafe OAM exposure via capsule dust that can be inhaled, lead to exposure of the eyes or hands, and contaminate the medication preparation area (Siden et al., 2014). Nurses must ensure that proper education regarding medication preparation and safe handling is initiated prior to the patient starting the medication and offer ongoing support in regard to OAM safety.

Standard educational programs for OAM are lacking. Nurses are positioned to institute process improvement programs specific to OAM treatment.

**KNOWLEDGE TRANSLATION**

- Nurses are positioned to assess family caregiver needs of patients prescribed oral anticancer medication (OAM) and to target supportive interventions accordingly.
- Family caregivers of patients receiving OAM are in need of education regarding safe handling of medication and bodily fluids/wastes, managing treatment interruptions, and seeking ongoing support and resources for financing OAM treatment.
- Further research is needed to determine the best evidence for family caregiver interventions specific to OAM management.

Nurses can be at the forefront of advocating for OAM educational programs that entail written patient/caregiver education and lend opportunity for patients and caregivers to practice preparing and administering OAMs. Providing caregivers with the chance to practice safe handling of OAMs in a controlled clinic environment can potentially increase confidence of handling OAMs in the home environment while allowing the opportunity to ask oncology nurses relevant questions. Such educational scenarios also provide nurses with the prospect of ensuring that caregivers are practicing safe handling and giving the opportunity to assess and address potential areas for intervention.

Nurses can help family caregivers address financial concerns by providing access to appropriate financial resources and/or referring patients and family caregivers to services for appropriate OAM funding. Patient and caregiver needs regarding OAM funding may change during the treatment trajectory and should be assessed at each patient or caregiver encounter. One caregiver noted that she had accepted OAM that had previously been prescribed to another patient from the oncology office. Certain prescription drug return, reuse, and recycling programs are available in some states and include anticancer drugs; however, these programs must follow specific guidelines (National Conference of State Legislatures, 2017). It is uncertain whether the medication accepted by this family caregiver met these guidelines, such as being sealed in the original, unsealed container and ensuring that the OAM was checked by a licensed pharmacist prior to redistribution (National Conference of State Legislatures, 2017). In addition, it raises concern regarding whether the OAM was properly stored prior to being returned to the oncology office, which could affect the integrity of the medication. Nurses should advocate for safe dispensing of OAMs and to ensure the financial concerns of patients and caregivers are met as they relate to OAM treatment.
Nurses can offer ongoing educational support to family caregivers during patient encounters and telephone discussions, propose web-based educational resource outlets, and act as liaisons between home-care nurses and family caregivers. Educational needs may include review of the medication safety issues, anticipated treatment interruptions, and financial resources. Future research, specifically on targeted educational interventions, is recommended to support the family caregiver’s ability to improve the care provided in the home for patients on OAM.

More research is needed to understand the impact of OAM on family caregivers and test interventions that support family caregiver needs. In addition, research that evaluates how treatment burden affects the relationships between informal caregivers and the patient over time is needed. Future research can use descriptive approaches using validated measures to quantify caregiver experiences and their perceptions of various oncology professional supportive interventions, such as telephone contact, web-based education, and face-to-face communication.

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Marshall contributed to the conceptualization and design. Marshall and Vachon completed the data collection. All authors provided the analysis and contributed to the manuscript preparation.

REFERENCES


QUESTION GUIDE FOR A JOURNAL CLUB
Journal clubs can help to increase and translate findings to clinical practice, education, administration, and research. Use the following questions to start discussion at your next journal club meeting. Then, take time to recap the discussion and make plans to proceed with suggested strategies.

1. The family caregivers in this study appear concerned and somewhat ill-prepared for their role in assisting their partner with oral anticancer medication. How can this be better addressed in busy clinics?
2. These partners experienced changes to their sexual relationship because of concerns or warnings about exposure to body fluids. How do you address this in practice and is this warranted?
3. The costs of oral anticancer and other medications are prohibitive for many families, particularly if they do not have insurance or are underinsured. How do you talk about the financial toxicities of cancer treatment with patients and their caregivers?
4. What effective approaches have you used to reduce the anxieties of caregivers when supervising or assisting their loved one in taking oral anticancer medication?

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