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Oral Oncolytic Agents –A Need for Research to Enhance Patient Centered?

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The Institute of Medicare has identified Patient Centeredness as one of the elements of quality health care delivery.^{1,2} ASCO through the Value in Cancer Care task force indicates that patient centeredness is important and that the “individual needs of the patient are paramount”.³ I offer here perspectives on patient-centered care related to oral oncolytics - the new approach to cancer therapy. Areas for needed research in consideration of the patient-centered perspectives⁴ are also offered.

Oral agents appear to be beneficial and convenient for patients. It would seem that the oral agents would prevent numerous trips to the cancer centers, prevent the cumbersome and painful aspects of intravenous chemotherapy, and be more favorable for patients. Is that so? We have limited documented evidence of what patients and families are experiencing and thus have limited information to guide our practice. Current studies on oral oncolytics appear to be limited to issues around adherence with such agents.^{5–8} More research is needed on met and unmet patient needs with this therapeutic approach.

The change in paradigm so that patients are responsible for obtaining and administering medication, monitoring for toxic effects, and long term maintenance treatment brings the need for new understanding, new standards, and new guidelines for nursing practice. There is less direct supervision, guidance and monitoring by the health care system to support patients and their family members. We need to develop systems of support for patients.

The prescription for the oral oncolytics often goes to a specialty pharmacy that prepares and mails or delivers the medication directly to the patient. Before the medications are mailed, the approval of the insurance company is needed for drugs that range from \$60,000–100,000 per year; this may take several weeks of negotiation. Thus, it may take 3–4 weeks from the time the prescription is written until the patient receives the drugs.

Patients experience many frustrations interacting with insurance companies, specialty pharmacies and drug assistance programs. Patients are seldom prepared for the copay of \$2,000–\$3,000 every month. Additionally, patients who are on oral agents are often at the age when they have multiple other chronic diseases being treated with medications. This can cause confusion with complex regimens and polypharmacy. Patients may be taking medication four or more times per day and 6–8 different medications per day. Warfarin, St.

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John's Wort, grapefruit, and high fat diets have been implicated as having drug interactions with oral agents. Research is needed on what strategies work best to assist patients with this complex situation.

Without all of the systems in place that we have for intravenous chemotherapy and radiation, patients and their families on oral agents do not have the educational materials and guidelines in place to manage the toxic effects so patients may develop serious side-effects. If instructions had been given, it may have been 15–45 days previous and thus patient confusion, uncertainty and forgetfulness occurs. With the toxicities, there are drug stoppage and dose reductions that cause further challenges for patients which adds to confusion.⁹

The new direction in cancer care - use of oral oncolytics - offers immediate opportunities for nursing research that go beyond adherence studies to developing the support needed by patients. For patients with solid tumors, many of the protocols are for patients with advanced disease who had lack of response to 2–3 other forms of therapy, thus the end of treatment options looms before them. The administration of medications is compounded by the different patterns of toxicities, large copays, monitoring for side effects and coordination of care. We need to examine our tested interventions for patients who receive traditional chemotherapy and radiation to see if some of the same cognitive behavioral or psychoeducational strategies will work for symptom management for patients on oral oncolytics. What problem solving and decision-making strategies would be assistive to these patients given the complex regimens? How do we help them with the judgments and decision making that is needed for obtaining drugs and obtaining insurance approval?

Patients on oral oncolytics are put in a position of greater autonomy, accountability and responsibility but is it patient centered? While some patients may appreciate a sense of empowerment, we find patients with advanced disease are overwhelmed by the side effects and complicated regimens. It appears that often our systems make a tacit assumption that patients will proceed with treatment without full discussion of benefits versus costs and toxicities. If these drugs are effective molecularly, what is the impact on the patient's emotional status and physical status and patient centeredness? Understanding patients' response and needed support to this complex new approach to treatment is essential. We need to develop evidence so that guidelines and standards of care can be tested, translated and implemented in clinical settings. We need to know what guidance patients need to be supported to initiate and continue treatment. The nursing science of care needs to catch up with this treatment approach.

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