



# The Research Connection

The Psychosocial & Nursing Advisory Board to  
the New Jersey Commission on Cancer Research

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The Joint Psychosocial and Nursing Advisory Group to the New Jersey Commission on Cancer Research (NJCCR) was appointed to advise the NJCCR of special research needs pertaining to nursing, psychology, sociology, and related disciplines for the purpose of addressing gaps in vital areas of cancer research and cancer care in New Jersey.

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## Issues in the Emerging Use of Antineoplastic Agents in Cancer Care

by

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The administration of oral chemotherapeutic agents is rapidly gaining momentum in cancer treatment. The impetus for the use of oral administration of antineoplastic agents is being driven by numerous factors, including patient convenience, Medicare Part D coverage, and the new focus on treating certain cancers as lifelong chronic diseases with the introduction of new technologies that allow practitioners to detect residual disease (Weingart et al., 2008).

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Patient preference for oral chemotherapy may be based on convenience or the belief that oral therapy is less toxic (Weingart et al., 2008). While oral administration is more convenient, greater responsibility for dosing and monitoring for side effects is placed on the patient and caregiver. The patient must correctly take the dose and report side effects to the clinician. This requires knowledge, understanding and accountability on the part of the patient and caregiver. In addition, the patient is responsible for disposing the antineoplastic agent in a safe appropriate manner. In the past 30 years, policies have been developed to safely dispose of intravenous biohazard materials. Precautions for the disposal of oral antineoplastic agents taken in the home will need to be developed (Weingart et al., 2008).

Safety in the dispensing of self-administered oral antineoplastic agents is another area that needs to be addressed. As outlined in the NCCN Task Force Report: Oral Chemotherapy (2008), Weingart et al. report that hospital pharmacies have multiple checks and balances incorporated into their medication administration process to improve safety by preventing medical errors. Community pharmacies and mail order pharmacies may not yet have these safety measures in place. In addition, many hospital pharmacies will only administer one day's dose or a few days dosage of the prescribed antineoplastic agent to reduce the risk of error in dosing. These policies may not exist in mail order pharmacies, which usually charge less for shipping larger quantities of prescription medications.

Adherence to therapy is another issue with self-administration. With infusion therapy, the practitioner is immediately aware of missed therapies and non-adherence to a given protocol. Self-administration requires the patient or caregiver to take responsibility and administer the medication as prescribed. Practitioners will have to be selective in deciding who the most optimal candidate for oral antineoplastic agents is. The NCCN Task Force Report: Oral Chemotherapy (2008), reports that adolescents, the mentally ill and individuals with low literacy levels are not ideal candidates.

Switching to oral administration requires oncologists, nurses and insurers to change their delivery of services. Infusion of antineoplastic agents in the outpatient setting has been a large source of

revenue for oncologists (Weingart et al., 2008). Nurses often assess and educate patients during infusion time. With self-administration, practitioners will see the patient less often, yet still need to provide the same assessment for toxicity and side effects. Effective communication, facilitation of patient/family/caregiver understanding, and adequate education should allow for positive outcomes. Practitioners and third party payers will have to agree on reimbursement for education and follow up.

In summary, pharmaceutical industries are investing substantially in the development of oral agents and undoubtedly, they will be prescribed more frequently in the future. While administration of oral antineoplastic agents offers advantages in terms of time and convenience, the need to change current health care practice is inevitable. Changes in the model of care delivery and inclusion of more patient safety initiatives will allow for an optimal transition to oral antineoplastic administration.

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## Managing Medications: Myths and Strategies

by

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Over 700,000 medication prescriptions are written by physicians and nurse practitioners each day. Research has shown that less than half of those medications will be taken as prescribed (DiMatteo, 2004b; Kripalani, Yao, & Haynes, 2007). Nonadherence with medication instructions contributes significantly to worsening of patients' health and results in increased hospitalization and health care costs (DiMatteo, 2004a; Osterberg & Blaschke, 2005). Individuals with chronic illness are particularly vulnerable to the effects of nonadherence as they are likely to be taking prescription medications for their conditions. Although medication adherence

remains difficult to study, the consensus among experts recommends that improving patient adherence behaviors will improve patient outcomes (Kravitz & Melnikow, 2004, p. 198).

Oral chemotherapy agents provide cancer patients with the convenience of being able to self-medicate, yet often have the same serious side effects as intravenous chemotherapy (Moore, 2007, p. 123). Oral medications are a part of daily life for those living with chronic illness and older adults with cancer often have other comorbid conditions, making their medication management more challenging for both the individual and the professional. The potential for diminished organ function and interactions with other medications in older adults is heightened (Goodin, Aisner, Bartel, & Viele, 2007, p. S34), making patient-provider communication essential for a patient's safe self-implementation of a prescribed treatment plan.

While oral chemotherapeutic agents have been used since the 1940s, intravenous therapy was the common route of administration for many years. The recent explosion of targeted therapies and use of oral routes of administration means that patients may no longer receive intravenous chemotherapy, where dosing and timing are controlled by the provider. The benefits of oral therapies to patients are many: more control over one's time and daily activities, fewer visits to the office or infusion center, and less discomfort from intravenous devices for infusions. Yet these conveniences can make communication between visits more challenging, for both patient and provider.

Studies examining the patient's perceptions of oral agents show that while patients appreciate the convenience of self-administration, they also feel that it is less effective (Grober, Carpenter, Glassman, & Blum, 2003, p. 746), heightening the importance of patient and family education. A patient's self-administration of oral chemotherapy means that the patient controls the timing and dosing of the medication. Teaching patients the importance of specific timing, dosing, handling of tablets and capsules, and reporting side effects requires more complex time-consuming teaching sessions than simply explaining treatment effects, symptom management and when to call the provider after an IV treatment.

A patient's adherence to an oral chemo regimen is an important focus of providers, and many providers request that patients bring their medication containers to visits so pills can be counted, and that patients keep a diary of when they take their medications (Goodin, et al., 2007, p. S35). Unfortunately, interventions to improve adherence with medications have had minimal impact on a patient's ability to manage their medications (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008). Dosing for oral chemotherapeutic agents can be quite complex, requiring medication to be taken before or after mealtimes, with a full glass of water, or other administration patterns (Moore, 2007, p. 124). Patients may misinterpret the importance of following a specific administration pattern, and although pill counts will be correct, the exact pattern may not have been followed.

The individual nature of human perception and sensation, combined with differing experiences of physiologic effects, make a uniform approach to understanding the experience of patient's management of their medication unrealistic. Rather, providers need to share information about medication actions and side effects in a way that patients can better understand these expected and potential sensations, and discuss with their provider their preferred level of desired sensations, and need to reduce or avoid intolerable sensations.

Patients with cancer have always dealt with the impact of their chemotherapy treatment, and have been responsible for managing their side effects at home, determining when to call the provider to report untoward symptoms. Cancer nurses need to ensure that an open dialogue exists between patients and providers to ensure that recommended administration patterns are followed, and appropriate self-management strategies are taught.

Providers need to anticipate that people will manage their medications in ways that are not as the provider intends: doses will be intentionally and unintentionally skipped, added, or taken on alternate schedules than recommended. Nurses can acknowledge in educational sessions that managing medications on a prescribed schedule is more difficult than it seems, and indicate that this is one of the topics that will be discussed on all future visits. The possible impact of missed doses should be explained, so that people can understand the physiological impact of

their choice. Providers need to listen for and recognize the self-care obstacles a patient might experience as possible medication choices are selected, as fewer doses per day is associated with improved adherence (Kripalani, et al., 2007, p. 542). A discussion of how patients have managed their medications in the past may suggest new strategies for self-management. Asking about lifestyle patterns, employment, social activities enjoyed, can provide opportunity for open dialogue that builds a strong relationship, a foundation for partnering in care, and an opportunity to address ways to manage medications in concert with an individual's patterns. In this case, active listening may be more important than prescriptions.

Providers must learn to work with people regarding the outcome that is desired by the person and take care not to *own* the patient's outcome. Acknowledging the individual's ability to choose their own health outcome allows providers to accept the role of a skilled and knowledgeable health adviser, rather than omnipotent provider. Although the notion of partnerships and patient empowerment is now accepted, there is evidence that providers resist patients' covert attempts to assert their experiential knowledge of their chronic condition, as a result of which providers fail to provide patients with the necessary resources to make informed decisions (Paterson, 2001, p. 576).

Nurses' ways of knowing and being with patients gives the profession an opportunity to describe to others the need to hear the voices and experiences of people living with cancer in a new way. Our role as teachers who help to translate the mysteries of medicine to patients must go beyond mere patient education regarding how a medication works and its potential side effects, to incorporate a deeper understanding of an individual's desired outcomes of care.

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## Oral Antineoplastic Agents

by

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Targeted therapy involving the use of monoclonal antibodies is becoming a standard part of clinical cancer treatment. Many newly approved agents are being formulated as oral agents for patient convenience. Monoclonal antibodies block the growth and spread of cancer cells by interfering with specific molecules, either inside the cell or on the cell surface, that are responsible for tumor growth or spread (Fessele, 2007). Oral cancer therapies offer many advantages, obviating the need for IV access and hospital or office visits while causing less severe adverse effects. However, responsibility for

administering treatment is shifted from physicians and nurses to patients and their family caregivers.

Adherence to long-term drug therapies is a complex and multifaceted issue that can alter the outcomes of therapy. Cameron (1999) divided all possible factors of non-adherence into five categories. The five categories are as follows:

- Patient's knowledge and understanding of the disease and treatment, e.g., lack of insight into illness; treatment of asymptomatic disease; adverse effects of medications; complexity of the regimen.
- Patient's beliefs about health, e.g., lack of belief in the benefit of treatment.
- Quality of the interaction between the patient and the health care providers, e.g., inadequate follow-up or discharge planning; presence of barriers to medications or care.
- Patient's social and financial resources, e.g., cost of medication, co-payment, or both.
- Factors associated with the illness and treatment, e.g., presence of cognitive impairment; presence of psychological problems, especially depression.

Adherence rates for many long-term drug therapies are 40-50% (Horwitz & Horwitz, 1993; Sackett & Haynes, 1976). A study that examined adherence to long term oncology treatment reported a highly variable adherence rate (Partridge, Avon, Wang, & Winer, 2002). Rates varied as follows: 17-27% for hematologic malignancies; 53-98% for breast cancer and 97% for ovarian cancer. Partridge, Wang, Winer, & Avon (2003) conducted a study involving 2,378 breast cancer patients who started adjuvant tamoxifen therapy between 1990 and 1996. Adherence during the first year of treatment was 87%, but declined significantly to only 50% after 4 years. These findings revealed that nearly one fourth of tamoxifen-treated patients were at risk for suboptimal clinical response due to poor adherence. Other studies have shown similar results (Partridge et al, 2002; Sharma & Saltz, 2000). With relatively few studies on patient adherence with oral chemotherapy, it is difficult to measure the prevalence of the problem (D'Amato, 2008).

Other challenges posed by oral cancer therapies include possible food or drug interactions, the potential for increased medication errors, high cost,

proper handling of oral antineoplastic drugs, which are more toxic than traditional self-administered oral agent, such as antibiotics and antihypertensive medications.

A multidisciplinary approach to education and assessment is critical to increasing patient adherence, since many factors contribute to this problem. Factors identified include lack of knowledge regarding medication's action, timing of dosing, side effects and importance of adherence to prescribed regime. Educating and involving patients in the process of making treatment decisions is very important, and health care providers must be able to recognize and address the patient's concerns about the treatment plan. Providing clear written instructions (dose, frequency, timing of dosing, what to do if a dose is omitted), side effects and management is vital for improving patient knowledge and safety. The importance of adherence and the possible ramifications of non-adherence with the treatment regimen allows the patient to participate in developing the care plan and to make an informed decision about compliance with the treatment plan. Inclusion of follow-up calls and scheduling of appointments to identify issues with treatment and evaluate patient responses to the plan of care should contribute to improved patient adherence rates and thereby improved outcomes. Health care providers must modify their current practice to incorporate patient need for education, assessment and follow up when the patient is self-administering oral antineoplastic agents.

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## Addressing the Financial Impact of Oral Chemotherapeutic Agents

By

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Fewer than 10% of chemotherapy drugs are currently available in oral form, yet projections from the National Comprehensive Cancer Network's Taskforce (NCCN) Oncology Report (2008) predict that this percentage will reach 25% by the year 2013. It is estimated that one-quarter of all anticancer agents under development now represent oral agents (Allen, 2007, p. 1).

The future use of oral chemotherapy drugs warrants consideration of financial costs. The actual cost of OCD's is exceedingly high. The average charge per 30 day supply of Xeloda exceeds \$2,000 and the charge for a monthly supply of Sutent approaches \$7,000 (NCCN, 2008). However, there are conflicting reports as to whether these high costs are offset by the decreased need for services, particularly oncology nursing staff and infusion centers (NCCN, 2008). One pharmacoeconomic analysis study found less need to treat patients for adverse events and greatly reduced costs in terms of patient time and medication resource utilization for OCD's (Cassidy, et al., 2006, p. 1122).

The realities of delivering oncology care, however have not consistently supported this cost saving notion. Administration of OCD's requires a significant amount of nursing time for patient education when beginning the regimen as well as frequent telephone consultation afterwards. In addition, in most practice settings, little if any time is

allotted for counseling patients about OCD's, nor is there typically either dedicated staff or space allocated for this activity. While some oncology practices offer written education materials or group education sessions, the more common practice is for education and counseling to be done on an "ad hoc" basis. The practice reality is that significantly greater continuous patient education will be required to ensure safe and effective administration of OCD's and it is completely uncompensated and notably underappreciated (NCCN, 2008).

There is also a financial impact of OCD's to revenues in private practices to consider. Historically, these revenues have been based on the delivery of parenteral therapy. With OCD's however, oncologists receive no revenue other than those from office visits required to monitor patient care. Additionally, while oncologists normally receive payment for administering parental chemotherapy, no similar payment is provided for administering OCD's (NCCN). The patient-physician relationship may be altered, with fewer oncology office visits and an increased need to coordinate cancer care with other entities, such as specialty pharmacies or clinics.

Another pharmacoeconomic analysis study suggested that these types of financial considerations may impact physicians' choices between oral and parenteral drugs when either would be clinically appropriate. Jacobsen, et al. (2006) analyzed the prescribing practices for chemotherapy according to physician reimbursement for treatment of Medicare beneficiaries with metastatic lung, breast or colorectal cancer treatments between 1995 and 1998 (p.437). Findings revealed that providers who were more generously reimbursed prescribed more costly chemotherapy regimens. However, when patients are burdened by copays for OCD's however, the financial incentives of providers can align with these patients.

Under the original Medicare Program (1965), there were specific criteria that covered only a limited number of drugs outside of hospitals/nursing homes. Those that are taken orally, self-administered, or given in doctors' offices were not covered by Medicare. Medicare Part D was developed under the Medicare Prescription Drug Improvement and Modernization Act of 2003 and dramatic changes that affect reimbursement for OCD's occurred. Part D provides coverage for certain prescription drugs, biological products, insulin and vaccines, although drugs that are

covered by Part A (hospital inpatient, nursing home, home health care and hospice) or Part B (physicians' services and chemotherapy administered on an outpatient basis) may be excluded from Part D. Part D is optional and requires patients to choose their prescription drug plan from more than 900 providers on the basis of which drugs are covered in the formulary, the cost of the plan, out-of-pocket cost of drugs obtained through the plan and the pharmacies participating in the plan. For a patient with Part D coverage, chemotherapy is covered by two different components of Medicare: Part B for parenteral therapy and Part D for oral chemotherapies. This dual system can be very confusing to both patients and physicians.

Patients' out-of-pocket expenses for medications vary under Part D depending on the individual's income, prescription drug needs and the plan chosen. No coverage is provided for spending between \$2400 and \$5451, a gap in coverage known as the "donut hole." Low income patients who receive OCD's may be able to avoid the donut hole by qualifying for various assistance programs. However, other patients without a low income often are affected by the donut hole because the high cost of OCD's can quickly become a financial hardship. These patients may obtain help in meeting their copay obligations from manufacturer patient assistance programs and patient advocacy foundations. In recent years, the assistance available through these programs has declined because of the mistaken belief that Medicare Part D eliminates the need for such assistance.

The above factors may affect the patient's attitude toward oral versus parenteral therapy. A patient who starts chemotherapy toward the end of the year will quickly experience the large "donut hole" expense and then will have the same expense during the following year. This type of situation might motivate patients in this situation to choose parenteral therapy initially and then request to change to oral therapy in the next year. Prescribing practices may also be affected by patients' desire to avoid multiple co-pays. Patients may request that their physician prescribe their OCD in a lower dose tablet so that if a dose reduction is required, the patient will not need to fill another prescription and pay another co-pay. Lastly, many patients who receive OCD's have difficulty paying their higher deductibles or the copays for their prescriptions and office visits. This may lead them to discontinue or inconsistently adhere

to their drug therapy, resulting in patients not completing their treatment, more emergency room visits and hospital admissions.

OCD's have been hailed as a convenient, less toxic form of therapy that will be driven by patient preference. There remain however many risks and benefits from the patient, physician and health care system perspective to be considered.

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## ANNOUNCEMENT



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