How the New Oral Antineoplastic Drugs Affect Nursing Practice

Capcitabine serves to illustrate.

OVERVIEW: The increasing use of oral anticancer drugs has profound implications for cancer treatment and nursing practice, shifting care from hospitals to outpatient settings and from oncology specialists to patients, families, and caregivers. Nurses will focus less on drug administration and more on educating patients, monitoring for adverse effects, and performing follow-up care. This article discusses how these new drugs are affecting nursing practice, focusing on one novel oral agent—capcitabine (Xeloda), approved for treating metastatic colorectal and breast cancer and as adjuvant therapy for stage 3 (Dukes’s C) colon cancer—to illustrate.

Several factors have fueled the development of oral anticancer drugs in recent years. First, people with advanced cancers are living longer. Reviews indicate that patients with metastatic colorectal cancer who receive both traditional and newer chemotherapies survive for a median of 20 months after diagnosis—almost twice as long as those receiving traditional chemotherapy alone. As a result, investigators are currently seeking less-invasive treatments that allow for a “reasonable” quality of life. Second, some patients may be taking anticancer or supportive drugs “on a continual basis for five, 10, or even 20 years,” making it important to keep costs down. And third, the rising incidence of cancer worldwide compounds the need to conserve medical resources.

Advances in computer imaging and nanotechnology have helped researchers develop oral antineoplastics despite such obstacles as difficulties in achieving consistent bioavailability and specific targeting capability. Current anticancer strategies and their respective oral agents include:

- Immunomodulation (bexarotene [Targretin], lenalidomide [Revlimid]).
- Targeted therapies such as protein tyrosine kinase inhibitors (imatinib [Gleevec], dasatinib [Sprycel], gefitinib [Iressa], erlotinib [Tarceva]).
- Therapies that capitalize on idiosyncratic aspects of tumor cells (capcitabine [Xeloda]).

Oral formulations make up about 5% of anticancer agents, but they represent up to 25% of all such drugs in development. Since March 2005, the Food and Drug Administration (FDA) has issued at least 15 approvals for new anticancer drugs and new indications for existing drugs. (For the latest updates, visit the [FDA website](http://www.fda.gov).)

This article discusses how these new drugs are affecting nursing practice, focusing on one novel oral agent—capecitabine, approved for treating metastatic colorectal and breast cancer and as adjuvant therapy for stage 3 (Dukes’s C) colon cancer. As of August, the National Cancer Institute’s clinical trials database (www.nci.nih.gov/clinicaltrials) listed more than 200 clinical trials involving the use of capecitabine alone or in combination with other agents. Some Oral Chemotherapeutic Drugs Available, page 45, lists a number of currently available oral chemotherapeutic drugs.

A LOOK AT CAPECITABINE
Chemotherapeutic agents can be classified by their chemical properties and mechanisms of action. Those classified as antimetabolites work by preventing cancer cells from making or using certain metabolites—organic compounds that are essential to cell functioning. This drug class includes both the traditional anticancer drug fluorouracil (also known as 5-FU; Adrucil) and its newer counterpart, capecitabine.

Antimetabolites closely resemble metabolites but are nonfunctional. Essentially, they act as decoys; the cancer cell attempts to use them as if they were metabolites, but to no avail. Many antimetabolites interfere with the production of DNA or RNA—for example, by inhibiting enzymes needed to produce nucleotides (the “building blocks” of nucleic acids) or altering the nucleotide sequence—thereby preventing replication and leading to cell death (apoptosis). Some antimetabolites, including both fluorouracil and capecitabine, are pyrimidine antagonists: they block production of a pyrimidine, an essential component of certain DNA and RNA nucleotides.

Fluorouracil is administered in bolus doses or by continuous infusion and is usually given with leucovorin, a folic acid derivative used to increase the effects of fluorouracil. This standard regimen is sometimes referred to as 5-FU/LV. Capecitabine is an orally administered produg—a substance that must be transformed metabolically to become active. After ingestion, capecitabine converts to fluorouracil in a three-step enzymatic process (see Figure 1, page 42). The last step involves thymidine phosphorylase, an enzyme present in higher levels in tumor cells than in healthy ones. Because active drug is produced within tumor tissue, capecitabine results in higher concentrations of active drug at the tumor site than fluorouracil. Capecitabine has demonstrated an efficacy at least comparable to that of a 5-FU/LV regimen.

Indications. The American Cancer Society (ACS) estimates that 112,340 new cases of colorectal cancer and 41,420 new cases of rectal cancer will be reported this year, along with more than 32,000 deaths combined. The ACS also projects that 180,510 new cases of invasive breast cancer and 40,910 deaths from breast cancer will occur. These figures represent all stages of illness.

In 1998 capecitabine was approved by the FDA as a first-line treatment for metastatic colorectal cancer when treatment with a fluoropyrimidine alone is preferred (fluorouracil and capecitabine are both fluoropyrimidines) and for treatment of metastatic breast cancer in combination with docetaxel (Taxotere) after treatment with anthracyclines has failed. In June 2005 the FDA expanded approval to include the use of capecitabine as an adjuvant therapy after surgery in cases of stage 3 colorectal cancer, based on results of the Xeloda in Adjuvant Colon Cancer Therapy (X-ACT) trial, a large, international, phase 3 clinical trial comparing capecitabine with bolus fluorouracil in the treatment of early-stage colon cancer.

Dosage and administration. The dosage of many chemotherapeutic agents is based on body surface area, given in square meters. The standard dosage of capecitabine is 1,250 mg/m² twice daily (morning and evening) for a total daily dosage of 2,500 mg/m², administered on a 21-day cycle (14 days of medication followed by seven days of rest). The drug is available in tablet strengths of 150 mg and 500 mg. Initial dosing regimens used both tablet strengths, but that can confuse patients and make accidental under- or overdosing more likely; moreover, when two strengths are prescribed, patients incur two copays. Marse and colleagues point out that the use of two strengths is unnecessary, since differences in patients’ metabolisms cause wide variation in plasma levels. Many physicians simplify the dosing regimen by using only 500-mg tablets. A total daily dosage of 3,500 mg, for example, can be taken as three 500-mg tablets in the morning and four 500-mg tablets in the evening.

The time at which a drug is taken and what it’s taken with can affect its absorption and metabolism and the risk of adverse effects. The manufacturer of capecitabine recommends that it be taken with food or within 30 minutes of a meal (its safety and efficacy data are based on administration with food). For patients who have difficulty swallowing or have a nasogastric (NG) or a percutaneous

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endoscopic gastrostomy (PEG) tube, the tablets may be crushed and dissolved in water for easier swallowing or tube administration. But capecitabine’s stability in solution and the drug’s efficacy when administered by tube are unknown; such cases should be referred to the manufacturer for guidance. The patient should drink two to three liters of fluid per day unless fluid restriction has been ordered.

ENSURING ADHERENCE

Before prescribing oral chemotherapy, the provider must consider the patient’s ability to adhere to the regimen; IV administration may be preferable in patients whose ability is in question or who don’t have caregiver support. But even capable and motivated patients may have difficulty with adherence. Administration of a drug intravenously affords nurses the opportunity for face-to-face contact with patients—and thus for monitoring and teaching—that may be lost with oral agents.

There’s little research on nonadherence among patients using oral chemotherapy. Many factors can play a role, including concerns about the drug, its possible adverse effects, and its cost; the inconvenience of the dosing schedule; and simple forgetfulness. Adherence is a complex matter—patients can range “from fully adherent to totally nonadherent, with most patients falling somewhere in between”—making nonadherence difficult to discern. In patients who aren’t responding to oral chemotherapy, nonadherence should be considered a possible cause. Other clues to nonadherence include missed office visits or failure to refill prescriptions. Patients may initially be reluctant to admit to nonadherence. A collaborative—rather than confrontational—attitude toward the patient is essential. Useful questions might include the following:

- “Some people have a hard time taking this medication as prescribed. Do you have any problems taking it or any other medication?”

Figure 1. How Capecitabine Works: A Three-Step Enzymatic Process

If taken orally, the anticancer drug fluorouracil (5-FU) is deactivated in the liver. But capecitabine (Xeloda), an oral antineoplastic, is metabolized into 5-FU in a three-step process beginning in the liver.

1. First, after being absorbed in the gut, capecitabine is delivered to the liver, where the enzyme carboxyl esterase changes it to 5’-deoxy-5-fluorocytidine (5’-DFCR), depicted here as a yellow cube.

2. A second enzyme, cytidine deaminase, then converts 5’-DFCR to 5’-deoxy-5-fluorouridine (5’-DFUR), shown here as yellow pyramids traveling through the bloodstream to cells.
Some ways to improve medication adherence might include a combination of education, counseling, reminders, self-monitoring tools such as a diary, and telephone follow-up by caregivers.

ENSURING PATIENT SAFETY
Intravenous chemotherapy is generally prescribed and administered by oncology specialists who know these drugs’ dosages and adverse effects. But oral chemotherapy can be prescribed in an office setting by nonspecialists and is self-administered. As a consequence, nursing practice shifts toward a greater emphasis on education, monitoring, and follow-up. Ensuring that the patient receives appropriate information when she or he receives the prescription is paramount.

As a precaution, a second person, such as a home health care nurse or a family member, should double-check doses before they are administered. Also, clinic or office staff and community pharmacists should collaborate, through meetings, telephone calls, and e-mails. The pharmacist might be the first to learn of a possible adverse effect (for example, if a patient taking capecitabine asks her or him to recommend an antidiarrheal) and can encourage the patient to contact her or his oncology specialist. And pharmacists can help nurses in detecting nonadherence or evaluating toxicity in patients.

The medication history can help reveal a patient’s hypersensitivity to a drug’s active ingredient or its derivatives. A complete blood count and a complete metabolic panel should be ordered with each cycle of chemotherapy, and more often than that for patients at high risk for myelosuppression (those on concurrent chemo- or radiotherapy; those with malnutrition, hepatic or renal dysfunction, or a history of myelosuppression; and older patients).

Capecitabine and its metabolites are excreted predominantly in the urine. Patients taking this drug, especially those with mild or moderate renal impairment, must have their renal function monitored. Patients with moderate impairment (a creatinine clearance rate of 30 to 50 mL/min) should receive 75% of the normal dosage; the drug should be held in those with severe renal impairment (a creatinine clearance rate of less than 30 mL/min). In a hospitalized patient, intake and output should be monitored. Hyperbilirubinemia is a frequent, though transient, adverse effect; liver function tests should be performed at the beginning of treatment and before each cycle starts. If moderate (or greater) elevations in bilirubin occur (1.5 to three times the upper limit of the normal range), administration should be interrupted until the condition diminishes or resolves.

MEDICATION INTERACTIONS
Drug metabolism usually involves various enzymes. One group, the cytochrome P-450 (CYP) enzymes, has been widely researched because they are involved in the metabolism of many drugs, including many
As the use of oral chemotherapies increases, new questions will emerge about treatment costs, insurance coverage, and reimbursement. Medicare and many commercial insurers currently reimburse providers only for oral antineoplastics that have an IV equivalent. The future of oral chemotherapy will depend in part on whether patients and providers are adequately reimbursed not only for the cost of the drug but also for the educational and monitoring services that are essential to effective management.

Social work and case management services may not be available in some ambulatory care and office settings. Nurses will be expected to help facilitate reimbursement for both the practice and its patients—for example, by working with office resources (such as the practice’s billing department) and specialty pharmacies and by exploring Medicare reimbursement guidelines, manufacturers’ patient assistance programs, and other resources such as AARP’s guide to Medicare’s prescription drug plans (www.aarphealthcare.com/MMADefault.aspx). Having an understanding of the cost-effectiveness of the new oral antineoplastics can be useful.

**Capecitabine.** In the Xeloda in Adjuvant Colon Cancer Therapy (X-ACT) trial, patients who received six months of adjuvant chemotherapy with capecitabine used fewer medical resources than did patients receiving standard IV bolus fluorouracil with leucovorin. A literature review reached similar conclusions, citing research indicating that patients taking oral capecitabine made fewer visits for drug administration, spent fewer days hospitalized, and required fewer staff hours than did patients receiving a standard IV regimen.

We informally surveyed three online U.S. pharmacies and found that the cost of one 500-mg capecitabine tablet runs from about $14 to $19; a 14-day cycle at a total daily dose of 3,500 mg would cost between $1,372 and $1,862. Most third-party payers, including HMOs, managed care organizations, and indemnity plan insurers, provide at least some coverage for capecitabine, as does Medicare Part B. But copays can be steep, and patient costs should be evaluated for their potential effect on adherence. (For information about coverage for capecitabine, visit the manufacturer’s resource center: www.xeloda.com/resource-center/xeloda-insurance-coverage.aspx.)

**REFERENCES**


**ANTINEOPLASTICS**

More than 30 years ago, pharmacists began preparing and administering oral chemotherapies. These medications were approved for oral administration and included vincristine, cyclophosphamide, and methotrexate, all of which were initially marketed as IV agents. However, oral routes of administration are now common for many antineoplastics. Moreover, genetic alterations in the CYP enzymes are common and can have profound effects on drug response. Care should be exercised when capecitabine is coadministered with other drugs—particularly the oral coumarin-derived anticoagulants such as warfarin (Coumadin and others) and the antiepileptic phenytoin (Dilantin)—that are hepatically metabolized by CYP2C9, one of the CYP enzymes. It's believed that capecitabine inhibits this enzyme's action, resulting in an elevated drug level and potential toxicities. Moreover, capecitabine's cyclic dosing schedule makes controlling drug interactions difficult, since the drug’s level in the body fluctuates.

**Warfarin.** Altered coagulation parameters, bleeding, and even death have occurred in patients taking oral coumarin-derived anticoagulants who began taking capecitabine. Significant increases in prothrombin time (PT) and international normalized ratio (INR) have also occurred. Using PT and INR to monitor anticoagulant response and adjusting the drug dosage accordingly is vital.

**Phenytoin.** No formal drug-drug interaction studies of capecitabine with drugs that are metabolized by CYP2C9 other than warfarin have been conducted. But toxicities associated with elevated phenytoin levels have been reported in some patients given capecitabine concomitantly with phenytoin. Phenytoin levels should be monitored and any change in seizure activity reported.

**Leucovorin,** often given with fluorouracil to increase its effect, is associated with increased acute dose-limiting toxicities (particularly diarrhea and hand–foot syndrome). It should not be given with capecitabine.

**Herbal preparations and over-the-counter drugs** are often used by patients; little is known about their efficacy or potential drug interactions.

**SYMPTOM MANAGEMENT**

Oral chemotherapy places more responsibility on the patient than an IV regimen does for recognizing and reporting adverse effects. Various dose-limiting toxicities and other adverse effects can arise, depending on the agent, the dosage, concurrently administered agents, and sometimes the method of administration. Among those most commonly seen with either IV or oral chemotherapy are neutropenia,
thrombocytopenia, anemia, nausea and vomiting, neuropathy, stomatitis, and dermatologic changes (such as rash). The National Cancer Institute’s method for grading adverse events (including toxicities) based on severity can be found at http://ctep.cancer.gov/forms/CTCAEv3.pdf.

Capecitabine’s toxicity profile is similar to that of fluorouracil administered by continuous infusion. Its dose-limiting toxicities include hand–foot syndrome and diarrhea, two of its most common adverse effects. However, fewer episodes of severe or life-threatening neutropenia, sepsis, and stomatitis occur with capecitabine than with IV bolus fluorouracil administration. Other common adverse effects of capecitabine are nausea, vomiting, and neutropenia. Capecitabine’s safety profile is favorable in both metastatic and postsurgical cases and in elderly patients.

Hand–foot syndrome is marked by painful reddening and swelling of the hands or feet (or both) and occurs more often with capecitabine than with IV bolus fluorouracil. Although the mechanism is unknown, it’s believed that hand–foot syndrome is related to drug metabolite accumulating in the skin, resulting in an inflammatory response. Exposure to heat (as from a warm shower or whirlpool) or repetitive pressure exerted on the hands or feet (as with activities like chopping vegetables or jogging) aggravate the condition. Early symptoms are numbness, tingling, edema, and pain. Patients may have trouble grasping objects or walking. If the capecitabine dosage isn’t adjusted or the drug isn’t stopped, the condition can progress to severe pain, ulceration, and moist desquamation. Early recognition and appropriate action are critical to management; there are no clinically proven prevention strategies. Treatment is focused on symptom management, but most of the evidence is anecdotal, and clinical trials are needed to demonstrate these therapies’ efficacy. Emollient creams, topical corticosteroids, the nicotine patch, vitamin B6 (pyridoxine), and vitamin E have reportedly helped in some cases. Nonsteroidal antiinflammatory drugs or opioids may help control pain. If recognized and managed early, symptoms can resolve in three to seven days.

Diarrhea is a common, potentially dangerous adverse effect associated with capecitabine as well as other chemotherapeutic agents, although it occurs less frequently with capecitabine than with the standard 5-FU/LV regimen. It must be reported and evaluated promptly to determine the cause. Patients often underestimate the seriousness of this symptom and fail to report it. The nurse should obtain a history of normal bowel habits to permit effective assessment of diarrhea, and patients should be encouraged to keep a daily log of any diarrheal episodes that occur. Patients experiencing grade 2 diarrhea—four or more bowel movements per day beyond the norm, or nocturnal stools—or worse should stop taking capecitabine immediately. If the drug is causing the diarrhea, it often can be safely restarted at a reduced dosage once the symptoms resolve. Diarrhea that continues for more than 24 hours after the drug is stopped requires clinical follow-up. Binding agents and antidiarrheals can help control symptoms, but their use should be discussed with the provider before administration.

Other gastrointestinal adverse effects associated with capecitabine include dyspepsia, nausea with or without vomiting, and stomatitis. Dyspepsia can be prevented or controlled with antacids or histamine H2–receptor antagonists such as famotidine (Pepcid) or ranitidine (Zantac). It’s unnecessary to adjust the dosage of capecitabine for patients receiving aluminum hydroxide or magnesium hydroxide preparations. Nausea and vomiting can be treated with low-dose corticosteroids, metoclopramide (Reglan), or serotonin 5–hydroxytryptamine3–receptor antagonists such as ondansetron (Zofran) or granisetron (Kytril). Stomatitis can be treated with saline

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**Some Oral Chemotherapeutic Drugs Available**

- bexarotene (Targretin)
- busulfan (Myleran)
- capecitabine (Xeloda)
- chlorambucil (Leukeran)
- cyclophosphamide (Cytoxan)
- dasatinib (Sprycel)
- erlotinib (Tarceva)
- etoposide (Vepesid)
- gefitinib (Iressa)
- hydroxyurea (Hydrea)
- imatinib (Gleevec)
- lapatinib (Tykerb)
- lenalidomide (Revlimid)
- lomustine (CeeNU)
- melphalan (Alkeran)
- methotrexate (Rheumatrex)
- mercaptopurine (Purinethol)
- mitotane (Lysodren)
- procarbazine (Matulane)
- sorafenib (Nexavar)
- sunitinib (Sutent)
- temozolomide (Temodar)
- temsirolimus (Torisel)
- thalidomide (Thalomid)
- thioquanine (Thioguanine Tabloid)
- vorinostat (Zolinza)
Patient Education Resources

Teaching tools should be evidence based, validated, culturally appropriate, and easy to use. Several tools have been developed specifically for capecitabine, including patient prescription guides, treatment diaries, and an interactive adverse-effect tool. These can be found online at the manufacturer’s resource center: www.xeloda.com/resource-center/xeloda-resources.aspx. Manufacturers of many other oral antineoplastics offer similar resources. The Web site www.oralchemo.org offers a guide to oral chemotherapy, lists questions patients may want to ask providers, and links to resource organizations worldwide. Here are some additional online resources:

- People Living with Cancer (www.plwc.org), a site sponsored by the American Society of Clinical Oncology, provides patient education materials ranging from guides to specific diseases and their treatments to help in finding clinical trials.
- The Oncology Nursing Society’s patient education page (www.ons.org/patientEd) links to online resources and has instructions for receiving some print resources.
- Patient support groups and community-focused organizations such as Gilda’s Club (www.gildasclub.org) and the Wellness Community (www.thewellnesscommunity.org) offer additional information and support.

Essential teaching regarding home-based oral chemotherapy should address

- how and when to contact providers.
- the drug’s dosage and administration schedule.
- If the regimen includes different tablet strengths, provide pictures of each tablet type with the administration time; instruct the patient to use a checklist to record completion of total daily dose.
- the signs and symptoms of adverse effects and what to do if they occur.
- the use of a diary or log to track the administration of doses, the occurrence of adverse events, and questions that arise between office visits.
- what to do about missed doses. (“If you miss a dose, don’t take twice the amount next time; just continue to take subsequent doses on schedule, as planned.”)

Take-home materials written in language that is appropriate to the patient’s level of comprehension can reinforce teaching. A literature review considering how information helps people with cancer adapt to treatment concluded that it can “enhance control and self-efficacy, promote self-care actions, assist in the amelioration of symptoms, and reduce anxiety.”13 But the same review also noted that, in some cases, it can lead to increased emotional distress and reduced adherence. Each patient’s information needs must be evaluated and patient education tailored accordingly. To avoid overwhelming a patient, the nurse might adjust the pace at which information is given, providing basic literature at the first visit and specialized information at follow-up visits. The time constraints under which most nurses work make patient education even more challenging. Innovative strategies, such as online education and automated e-mail delivery of treatment-related reminders, are warranted. For more, see Patient Education Resources, at left.

Patients taking capecitabine should be instructed to take it with food or within 30 minutes of a meal. Explain that the tablets should be swallowed whole—not chewed, crushed, or dissolved, unless they must be to permit swallowing or NG or PEG tube administration. If the tablets must be crushed or dissolved, safe handling precautions must be taught to minimize the risk of exposing others to the drug’s toxic effects. To ensure adequate hydration, instruct patients to fill two or three one-liter bottles every morning and carry one at all times, checking intake periodically by counting how many full bottles remain. Commercially available flavoring packets can be used to afford variety.

Early reporting of signs and symptoms of adverse effects is critical to both symptom management and patient safety. Encourage patients to keep a daily log and promptly report any changes in urinary or fecal elimination, as well as symptoms indicative of rinses four times daily; other treatments such as frequent cleaning with a soft bristle brush and moisturizing the mouth with a water-soluble lubricating jelly may also be helpful.12 Patients should avoid spicy foods and acidic fruits to minimize discomfort.12 Capecitabine sometimes causes itchy or dry skin; this can be treated with hydrating creams and emollients. Other complaints may include fatigue, dizziness, headache, fever, pain, sleeplessness, and decreased libido. Energy conservation measures and additional medications may be required for symptom management. Alopecia is rare and may be the result of prior or concurrent chemotherapy. The need for cosmetic support (such as wigs or scarfs) should be evaluated on an individual basis. Some patients may benefit from a cosmetic support program such as Look Good Feel Better (www.lookgoodfeelbetter.org).

PATIENT EDUCATION

The ability to process and assimilate new information varies widely among patients. Nurses must be able to assess a patient’s knowledge and needs and then adapt the necessary information accordingly.
Patients may underreport treatment-related symptoms, believing that a reduction in dose would jeopardize its effectiveness.

(painful redness and swelling of the hands or feet or both; discomfort that interferes with activities of daily living) or worse should stop taking capecitabine until their condition can be evaluated.

To minimize the risk of drug–drug interactions, advise patients to share their treatment regimen with all of their providers. Patients taking coumarin-derived anticoagulants should be counseled to report signs and symptoms of unusual bruising or bleeding immediately. Counsel patients to check with their primary care provider or pharmacist before adding vitamins, herbal supplements, or over-the-counter medications to their regimen, because little is known about potential interactions.

To improve or maintain adherence, encourage patients to develop their own systematic approach to taking medications by, for example, keeping a daily log or posting a reminder on the refrigerator. The manufacturer of capecitabine offers a free treatment diary (www.xeloda.com/pdf/your-xeloda-therapy.pdf); many manufacturers of oral antineoplastics offer similar tools.

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REFERENCES


**GENERAL PURPOSES:** To explore how the new oral antineoplastic drugs affect nursing practice, using the agent capecitabine to illustrate.

**LEARNING OBJECTIVES:** After reading this article and taking the test on the next page, you will be able to
- explain the similarities and differences between oral chemotherapy and other types of cancer treatments, along with its actions and outcomes.
- outline the key factors involved in administering oral antineoplastics.
- plan an education program for patients taking oral antineoplastics.

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