# Program to Support Safe Administration of Oral Chemotherapy

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Drugs, particularly direct cytotoxics, prescribed for the treatment of patients with cancer often are characterized by their narrow therapeutic indices. During the last decade, the medical literature has been replete with evidence of heightened concern regarding chemotherapy safety.[1-10] Numerous institutions, including ours, have thoroughly reviewed and subsequently revised chemotherapy policies and procedures to improve medication safety and elevate the standard of care.[3,6,11] The resultant improvements typically have taken place in the inpatient and clinic settings, where chemotherapy administration is managed entirely by health care professionals. Chemotherapy process improvements at Dartmouth-Hitchcock Medical Center (DHMC; Lebanon, New Hampshire) during the late 1990s included order-set development, staff education, restrictions on personnel involved in the process of treating patients with chemotherapy, and multidisciplinary double- or triple-checks of dose calculations, regimen, and laboratory values. These improvements are similar to those made at other institutions.

It is a widely held belief that the intravenous route of medication administration presents the greatest risk of toxicities and other adverse events; however, consideration of oral cytotoxics as benign drugs would be ill advised. Recently published reports of morbidity and mortality associated with oral chemotherapy use demonstrate the need for due caution when chemotherapy is administered by any route. For instance, a patient who should have received temozolomide 320 mg daily for 5 days died of leukopenia-related sepsis after erroneously taking the drug for 22 consecutive days.[12] Another report describes a patient for whom a dose of lomustine was prescribed to be taken once every 6 weeks. The prescription vial was mislabeled and the patient died after taking the drug every day for 3 weeks.[13] Finally, a patient was hospitalized after taking lomustine 160 mg once daily for 5 consecutive days, rather than a single dose. This patient's pharmacist had dispensed a full package of 20 capsules, 40 mg each, to avoid leaving a potentially unusable partial package on the shelf. These are only three examples of a serious problem that is very likely under-reported, as are medication errors in general.

At DHMC, a multidisciplinary group convened in 2001 to evaluate the use of oral chemotherapy administration in all settings, and to devise a plan for process improvement. This committee designed and implemented a program built around the following elements, to monitor patients who receive oral chemotherapy in the home:

- An oncology-certified registered nurse (RN) was assigned to establish telephone contact with each patient. An oncology pharmacist provided backup to perform these duties when needed.
- The program was publicized, promoted, and limited to the section of adult hematology and oncology.
- A tracking method was devised to determine what proportion of patients receiving oral chemotherapy were identified to the nurse educator and how many of these patients were contacted successfully, and to identify any issues or problems with the patient's understanding of the medication management or accuracy of the filled prescription.

During each phone conversation, the nurse reviewed the medication order and compared drug name, dosage, frequency, and duration with the prescription vial in the patient's possession. The nurse elicited evidence of patient understanding of the chemotherapy regimen, and investigated any potential barriers to a successful course of therapy. Data collected from June 2002 to December 2003 reveal that 211 patients taking oral chemotherapy were identified as participants for the phone call follow-up program. Adjusting for patients who received multiple cycles, 377 patient calls were attempted. Of these attempts, there were 20 times that patient contact could not be established (5.3%). The RN was unable to communicate with one patient because of an insurmountable language barrier. Thus a total of 356 phone conversations took place between the oncology nurse and patients for whom chemotherapy had been prescribed during this period. A potential problem was identified indicating a need for further counseling and/or corrective action in 64 (18%) of the phone calls. Table 1 quantifies and categorizes problems and concerns revealed during these encounters.

The nurse or pharmacist was frequently able to discover specific adverse drug effects not otherwise reported by the patient. Actions taken to minimize adverse effects and to provide symptom management were reported through the program and documented in the medical record.

There were several reports of patients who misunderstood the length of an oral chemotherapy cycle. Presumably, without the intervention provided by the nurse, these patients would have continued taking cytotoxic medication for prolonged periods.

Dispensing practices that may undermine safe oral chemotherapy administration were revealed. Third-party payers, indigent-patient programs, mail-order pharmacies and other suppliers sometimes promote or demand prescribing and dispensing in amounts greater than required. Small independent pharmacies may have only a single patient taking a particular oral chemotherapy drug, and may find it fiscally imprudent to fill a pre-

**Table 1. Problems and concerns revealed during 356 phone encounters**

| Results | No. |
|---|---|
| Referrals and calls | |
| No. of patients referred to oral chemotherapy follow-up program | 211 |
| No. of chemotherapy patient cycles | 495 |
| No. of contacts attempted | 377 |
| Unable to reach patient by phone | 20 |
| Unable to communicate with patient (language barrier) | 1 |
| Problems documented | |
| Pharmacy did not dispense drug in daily dose packs if indicated | 13 |
| Incomplete/incorrect instructions on label of vial/bottle | 12 |
| Problems with insurance including co-payment | 8 |
| Pharmacy dispensed incorrect amount of drug | 6 |
| Patient misread/misinterpreted instructions on label | 6 |
| Patient noncompliant | 6 |
| Patient/family confused and need additional help to understand instructions | 5 |
| Clarified expected adverse effects and treatment plan | 5 |
| Patient still myelosuppressed, requiring chemotherapy to be held | 2 |
| Discrepancy between prescription and planned regimen per office note | 1 |
| Total No. of problems | 64 |

NOTE. Extracted from the oral chemotherapy phone call log for the period June 2002 to December 2003. Phone conversations are planned to take place within 24 to 48 hours of the first day of an oral chemotherapy cycle.

scription that leaves a partial bottle remaining on the shelf. Under such circumstances, prescribers may feel there is no choice but to order amounts of drug in excess of the requirement for a single cycle.

High copayments, restricted access to expensive medications, and limited access to pharmacies of choice are some of the barriers faced by our patients. A Medication Assistance Program (MAP) has been developed at DHMC to help patients navigate complex reimbursement issues. A joint effort of physicians, social workers, nurses, and pharmacists, the MAP oversees receipt, storage, and dispensing of medications donated to patients via indigent-patient programs.

We believe that these results should be of interest and concern to those who care for patients receiving oral chemotherapy. We encourage physicians to write nonrefillable prescriptions, only for the amount of medication necessary to complete one cycle of treatment. We appeal to leaders in the pharmaceutical industry and third-party programs to provide oral chemotherapy medications in a way that supports dispensing of safe and appropriate amounts. We recommend further investigation into strategies for safe administration of oral chemotherapy. Scientific studies of the impact of education and counseling methods on compliance and adverse events would be of particular interest. We encourage researchers to investigate possible relationships between social or demographic factors and the ability to manage self-administration of oral chemotherapy. In addition, CNS diagnoses or comorbidities may impact cognition, memory, and the ability of the patient to understand instructions and comply with oral chemotherapy. Clinical trials testing this hypothesis would be of value, as would attempts to validate interventions intended to improve understanding and compliance in these patient populations. Until further information is available, support systems such as the program described may be a valuable addition to standard education, counseling, and monitoring of each patient for whom oral chemotherapy is prescribed.

***Authors' Disclosure of Potential Conflicts of Interest***
*The authors indicated no potential conflicts of interest.*

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