

Safe Handling and Administration Considerations of Oral Anticancer Agents in the Clinical and Home Setting

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The use of hormonal, chemotherapeutic, and targeted biologic oral agents has exponentially increased since the early 2000s. Oral therapies have the advantage of persistent exposure of the cytotoxic drug to tumor cells and the tumor environment. The use of oral anticancer agents provides therapeutic drug treatment for patients with cancer in the comfort of their home or alternative settings, such as retirement homes and assisted living or extended-care facilities. Practices to ensure safe storage, handling, administration, and disposal of oral agents are necessary to prevent additional exposure of hazardous substances to the environment, professionals, patients, family members, and caretakers. Providers should consider potential barriers to adherence and compliance, and develop strategies to ensure optimal therapeutic benefit prior to initiation of oral agents.

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The continued development of oral anticancer therapies is fueled by ease of administration, absence of hospitalization or clinic visit, acceptable disease outcomes, potential decrease in side-effect profiles, patient satisfaction, less interference in work and social activities, and the paradigm shift that views cancer as a chronic condition (Hohneker, Shah-Mehta, & Brandt, 2011; Moore, 2010). Daily low-dose or episodic scheduling of oral chemotherapeutic agents may reduce the dose-limiting side effects, including marrow toxicities, that are common with bolus IV dosing (Hohneker et al., 2011; Moore, 2010). Oral targeted biologic agents may be prescribed as monotherapies or added to chemotherapeutic regimens, often with few side effects (Weingart et al., 2008).

Information about safe handling and disposal should be incorporated into professional, patient, and family education. Standard operating procedures should be in place at every institution to educate patients and family members about safety. Sustaining biohazard safety guidelines and preventing contamination of landfills and water supply is essential (Bartel, 2007). Potential adverse events should be monitored for individual and group effects, with explanation of the adverse-event profile to patients.

Literature Review

An electronic literature review was conducted using PubMed, CINAHL®, Web of Knowledge, Access Medicine, Scopus, and Cochrane Library from 1984–2011 with key words such as *chemotherapy, chemotherapeutic agents, oral, antineoplastic, safety, errors, adherence, education, safety standards, and guidelines* to identify publications with evidence-based data or guidelines. Fifty articles were retained that described evidence-based aspects of care for the safe administration and handling of anticancer oral agents. Standards of practice or guidelines were identified from the American Society of Health-System Pharmacists (ASHP), American Society of Clinical Oncology (ASCO), British Oncology Pharmacy Association (BOPA), National Comprehensive Cancer Network (NCCN), Occupational Safety and Health Administration (OSHA), Oncology Nursing Society (ONS), and Society of Hospital Pharmacists of Australia (SHPA) (see Figure 1). In addition, an international board of pharmacists reviewed existing policies, publications, and best practices to determine recommendations for safe handling of oral chemotherapeutic agents for manufacturers and distributors, healthcare providers, patients, and caregivers (Goodin et al., 2011).

Safe Handling

In response to concern about the safe handling of anti-neoplastic drugs, OSHA (1999) defined a hazardous drug as any chemical that may cause a physical or health hazard and provided an extensive list of hazardous antineoplastic IV, injectable, and oral agents, with inclusion of hormonal drugs such as diethylstilbestrol, estrogen products, megestrol, and tamoxifen. OSHA (1999) recommended special handling with concern for acute and chronic workplace exposure. The degree of absorption that takes place at work and the resulting biologic effects are difficult to measure; however, OSHA maintained that those drugs require special handling to minimize short- and long-term effects. Accidental exposure of oral anticancer drugs can occur during transportation, unpacking, storage, handling, administration, and disposal; therefore, guidelines are necessary for those activities (Birner, Bedell, Avery, & Ernstoff, 2006; Goodin et al., 2011). Figure 2 provides a list of commonly prescribed oral anticancer drugs; however, the list is not inclusive of all therapies or investigational agents (Barton, 2011; OSHA, 1999; Prostate Cancer Research Institute, 2011).

Policies

Policies about the safe handling of IV chemotherapeutic and biologic agents in the traditional setting of the office or hospital are common to ensure minimal exposure to cytotoxic and hazardous substances. Less common are policies related to the safe handling of oral therapies (SHPA, 2007; Spoelstra, Given, & Grant, 2011). Oral chemotherapy carries the same risk as parenteral preparations in terms of toxicity and the potential for harm because of a narrow therapeutic index (SHPA, 2007). Although the risk of exposure to oral anticancer therapies may be minimal, safe handling still is recommended to avoid skin contact and inhalation of medication powder (SHPA, 2007). Community nurses and home nursing agencies should be included in education efforts about oral drugs and safe-handling practices. Patients can assist in maintaining a safe environment by returning any unused drugs to the pharmacy for proper disposal (Cooper & Depledge, 2004).

Protection of Nurses

Nurses working on general units outside the oncology setting also often are exposed to oral anticancer agents. If continually exposed without proper precautions, those nurses may increase their risks of contact dermatitis, liver damage, spontaneous abortion, or respiratory tissue damage (OSHA, 1999; Wilkes & Barton-Burke, 2011). Skin, eyes, and mucosa are sites of possible irritation from surface- or direct-contact contamination, inhalation, and ingestion. Oral agents should not be crushed and capsules should not be opened to avoid harm to the person handling the drug. Patients should be reminded not to disturb the drug's integrity and to avoid chewing those agents (SHPA, 2007). If a patient experiences impaired oral intake, the pharmacy should be notified for emulsification of the agent (Lam, 2011; Simmons, 2010; Weingart et al., 2008).

The level of protective wear for the administration of oral anticancer agents is relatively unknown; however, people who

Safe Handling

- Avoid opening capsules and breaking or crushing tablets.
- Transdisciplinary patient education about disease and drug with specialty pharmacist or trained nurse
- Patient education about health-system policies
- Professional training with ongoing competencies for anyone handling drugs and waste products
- Cytotoxic labels on all containers or boxes that hold anticancer drugs
- Patient under the care of specialist oncology staff
- Safe-handling policies already in place
- Handle oral chemotherapy in same manner as IV chemotherapy; gloves and handwashing at minimum by nurses.
- Proper handling of waste at home

Administration

- Proper labeling of drugs, including route, dose, and time
- Avoid "use as directed" on prescription.
- Detailed treatment calendar for patient
- Medication reconciliation, including over-the-counter drugs, by provider
- Patient to report medication errors, lapses, and side effects to provider
- Double and triple check for oral agents instituted by nurses and in pharmacy
- Patients to bring in medication bottles to monitor adherence
- Electronic record keeping
- Dose modifications clearly identified, perhaps standardized
- Patient seen by provider before every cycle; frequency of visits outlined
- Verbal and written education for patient, family, and caregiver
- 24-hour telephone access
- Informed consent that serves as contract between patient and provider

FIGURE 1. Commonly Used Guidelines for Safe Handling and Administration of Anticancer Agents

Note. Based on information from British Oncology Pharmacy Association, 2004; Goodin et al., 2011; Grampians Integrated Cancer Service, 2008; Jacobson et al., 2009, 2012; Oakley et al., 2010; Weingart et al., 2008, 2011.

administer oral agents should wear gloves, avoid direct contact with the pill or capsule, and wash their hands prior to and after the drug administration (SHPA, 2007). Prior to the administration of liquid medications via oral or enteral tube routes, nurses should put on protective wear, including gown, gloves, and eye protection (ASHP, 2002; Simmons, 2010). Women who are pregnant or trying to conceive should consider transferring to another ward or unit and avoid administering oral agents. Best practice supports the standard measures of gloves, gown, mask, and eyewear for cleanup of significant oral agent spills to avoid direct contact with powder and inhalation dust (SHPA, 2007; Simmons, 2010).

Protection of Patients, Family, and Caregivers

If medications are delivered to the home, courier services should be appropriately licensed to carry hazardous substances. Patients should be advised by their pharmacist or nurse on what action to take if a delivery does not occur, the packaging is damaged,

or the drug appears compromised. Tracking and reporting of delivery issues are essential to risk management (Cooper & Depledge, 2004). Patients should be educated about any requirements for storage, such as temperature or light-resistant needs. The patient, family, and caregiver also should be instructed on safe practices with administration of oral chemotherapy, adjustments in dosing, or return of drug to the pharmacy or oncology clinic. Patient education sheets should be available to enhance verbal instructions with reinforcement that oral anticancer agents are toxic substances (Moody & Jackowski, 2010).

Administration of Oral Agents

The prescribing, dispensing, and administering of oral anticancer agents include precautions that can enhance accuracy, adherence issues, and toxicity documentation. Oral anticancer agents represent emerging risk areas and require appropriate professional and lay education about a drug's side-effect profile, role in disease management, proper administration, and adherence to the planned regimen (Jatoi et al., 2010; Schneider, Hess, & Gosselin, 2011). Evidence-based practices in place for IV anticancer agents should be considered for all oral agents to promote a culture of safety. The avoidance of errors or near-misses is imperative; mistakes with any anticancer drug may have deleterious effects, even when only one or two changes occur in a prescribed drug cycle (Jatoi et al., 2010).

Prescribing Precautions

Tools that can provide optimal outcomes when prescribing oral anticancer agents include policies and electronic medical records. Oral agents should be prescribed routinely on chemotherapy order sheets in the same manner as IV chemotherapy, with provision of height, weight, calculated body surface area, age, laboratory values, and clear instructions for the dosage and administration of the drug (Grampians Integrative Cancer Service, 2008). For institutions without electronic medical records, this form may be generated on a unit-based computer program with

typed entries to avoid interpretation errors. Medication reconciliation must occur for current medications with documentation of oral anticancer therapy (SHPA, 2007; Weingart et al., 2008). Prescribed information should be verified by two pharmacists prior to dispensing and two nurses prior to administering. Some institutions have implemented a triple-check system, including three pharmacists and three RNs, prior to the administration of any antineoplastic agent (Jatoi et al., 2010).

Most oral anticancer agents can be filled at any pharmacy; however, standard chemotherapy order forms do not typically exist in the retail setting (Weingart et al., 2008). All pertinent information should be relayed in a readable format; provider abbreviations may hinder an understanding of instructions. Local pharmacists may not be as familiar with oral agents and, therefore, may not provide accurate detailed instructions for the patient. Mail-order pharmacies may provide a three-month supply of a drug or automatic refills with no safeguards in place if oral therapy is recalculated, stopped, or changed (Weingart et al., 2008). Those potential scenarios reinforce the importance of detailed education by the oncology team, including simplistic calendars and detailed written instructions for disposal of hazardous medication. When possible, prescriptions should be filled at specialty pharmacies that are equipped with pharmacists trained in oncology procedures and drugs (Jatoi et al., 2010); however, collaboration with the referring oncology team may enhance local pharmacy use.

Accuracy

IV chemotherapy medication errors have significantly decreased because of built-in checks and balances from pharmacy to the bedside (Weingart et al., 2008). Such rigid checks typically are not in place for oral chemotherapy orders, even in hospital pharmacies. In a study of medication errors in adult and pediatric populations by Walsh et al. (2008), the most common errors in drug administration were noted in the adult clinic and the pediatric home setting. A study by Weingart et al. (2007) of 42 comprehensive cancer centers in the United States revealed that few routine safeguards are in place for oral chemotherapy orders. Common indices such as body surface area were not included on 66% of oral chemotherapy orders, and only 25% included the patient's diagnosis or protocol information (Weingart et al., 2007). Few institutions (20%) required a double check by a second clinician, and only 10% required inclusion of the treatment cycle. Serious adverse drug events with oral chemotherapy voluntarily were reported at 25% of the institutions; 33% reported serious near-miss errors (Weingart et al., 2007). Few institutions reported safety precautions to monitor and manage risks associated with oral chemotherapies (Weingart et al., 2007).

A proactive risk-assessment study of oral chemotherapeutic drugs by Weingart et al. (2007) was performed at a comprehensive cancer center in the pediatric and adult clinics. Failure mode and effects analyses were performed for five oral chemotherapy agents used by ambulatory patients, including capecitabine, imatinib, temozolomide, 6-mercaptopurine, and an investigational agent (Weingart et al., 2011). For each drug, major steps were examined with a focus on the prescribing, dispensing, administering, and monitoring stages of medication use (Weingart et al., 2011). Four high-risk failure modes were identified for all five drugs: prescription writing errors, wrong

Chemotherapy

Busulfan, capecitabine, chlorambucil, cyclophosphamide, etoposide, hexamethylmelamine, lomustine, melphalan, methotrexate, procarbazine, and temozolomide

Targeted Agents

Dasatinib, erlotinib, everolimus, gefitinib, imatinib, lenalidomide, nilotinib, pazopanib, sorafenib, sunitinib, and thalidomide

Hormonal Agents

Abarelix, aminoglutethimide, anastrozole, bicalutamide, cyproterone, diethylstilbestrol, dutasteride, exemestane, estramustine, finasteride, goserelin, leuprolide, letrozole, megestrol, nilutamide, and tamoxifen

FIGURE 2. Examples of Hazardous Oral Anticancer Drugs by Classification

Note. Based on information from Barton, 2011; Occupational Safety and Health Administration, 1999; Prostate Cancer Research Institute, 2011.

Implications for Practice

- ▶ Oral antineoplastic agents require the same safe-handling and administration procedures as their parenteral versions.
- ▶ Safe administration and handling of oral agents should be taught to healthcare providers, patients, and caregivers with written instructions.
- ▶ Patients often prefer regimens with oral agents as compared to parenteral protocols; therefore, expanded education about compliance and potential side effects should be provided to patients, family, and caregivers.

medication or amount dispensed at pharmacy, suboptimal adherence by the patient, or failure of the patient to report adverse effects (Weingart et al., 2011).

Adherence

Noncompliance and lack of adherence may negatively affect the ability of a prescribed regimen to control or eradicate a cancer (Patton, 2008). Adherence to anticancer agents has become problematic because of the increased amount of agents and duration of use, the advent of oral biologic and targeted agents, increased combinations of oral therapy with varying patterns of administration, poly-pharmacy, and the older baseline age of patients with cancer (Maloney & Kagan, 2011; Moore, 2010). Other barriers related to adherence include poor communication, use of retail pharmacies, economic and reimbursement issues, motivation, and disease or treatment complexity (Hohneker et al., 2011; Simchowitz et al., 2010). Documentation of adherence remains an issue because no method is fail-proof or completely accurate. Suboptimal adherence to a regimen may lead to ineffective outcomes of treatment, drug resistance, and altered response to therapy with resulting disease progression (Moore, 2010). In some instances, poor adherence can be associated significantly with increased risk of death (Thompson, Dewar, Fahey, & McCowan, 2007). Persistence, adherence to duration of therapy, and compliance to the prescribed regimen may be challenging but are central to optimal outcomes (Hohneker et al., 2011).

Clinical trials of patients with multiple chronic disease states have recorded adherence issues with oral therapies, including management for HIV, diabetes, cancer, and heart failure (Mattson & Friedman, 1984; Moore, 2010). Adherence issues are common with complicated regimens and patients with significant socioeconomic issues (Moore, 2010; Patton, 2008). Although some patients may welcome the autonomy and sense of empowerment with oral treatment, other patients may struggle with the added responsibilities. Oral treatment may not be ideal for patients who are very ill, have complicated dosing regimens, or live alone with minimal assistance. Patients with cancer have documented adherence as low as 20% in some cases (Partridge, Avorn, Wang, & Winer, 2002). Adherence rates can sequentially decrease over time, resulting in decreased persistence and total amount of drug used (Partridge, Wang, Winer, & Avorn, 2003).

Overadherence also can occur in patients with cancer who intake more medication than is prescribed or continue a medi-

cation without interruption, which may occur when patients are fearful of disease progression and death, or are intentionally unaware about dosing or toxicity profiles. Debilitating side effects sometimes are endured silently when patients maintain therapy that has been otherwise discontinued or interrupted (Palmieri & Barton, 2007). The advantages and disadvantages of oral therapy must be negotiated among the provider, patient, family, and caregiver to ensure optimal adherence with regard to personal circumstances (Weingart et al., 2008).

Toxicity Documentation

The side-effect profile offers important data to the clinician as well as the researcher. Appropriate and accurate data collection must occur to evaluate the effect of treatment, toxicity profiles, drug safety and tolerability, dose-response relationships, pharmacokinetic parameters, and optimal dose intervals and frequencies (Warren et al., 2011). Limitations in adherence reporting, self-management of drugs, abandonment of treatment, and loss to follow-up may reduce the efficacy of intervention (Faiman, 2011; Streeter, Schwartzberg, Husain, & Johnsrud, 2011) and confound therapeutic or clinical trial results.

Patients may minimize experienced symptoms over a two- to three-week period; if the clinic visit interval is greater than three weeks, patients may possibly forget symptoms. A mechanism of side-effect reporting is essential to capture patient-reported outcome data and may include a simple diary. Several studies have been conducted on reporting and documenting mechanisms, including the use of electronic methods for data capture and communication, from personal digital assistant devices to computerized logs and automated telephoning (Matthew et al., 2007; National Cancer Institute, 2011). Education must be provided to the patient, family, and caregiver with clear definitions of anticipated side effects and parameters for when to contact the provider's office. The oncology nursing staff may consider an ongoing review of patients receiving oral chemotherapy with episodic phone calls. A 24-hour access phone number, including weekend hours, is essential for a practice that uses oral agents.

Conclusion

This comprehensive review of published evidence provides data to support safe-handling and administration procedures for oral agents. Strategies to improve accuracy, adherence, and toxicity documentation must be developed and tested, particularly in clinical trial settings when outcomes predicate the future care of patients. Registered and advanced practice nurses are integral to improving the safe handling and administration of oral anticancer agents and should ensure standard operating procedures.

Exploration on the Go



Learn more about the safety practices surrounding oral anticancer agents by enrolling in the Oncology Nursing Society's online course, *Oral Therapies for Cancer*. To access, open a barcode scanner on your smartphone, take a photo of the code, and your phone will link automatically. Or, visit www.ons.org/CourseDetail.aspx?course_id=93.

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