
THE CHALLENGES OF ORAL AGENTS AS ANTINEOPLASTIC TREATMENTS

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OBJECTIVES: *Given the increasing use of oral antineoplastic agents in cancer management, patient adherence is critical to successful treatment outcomes. This article reviews the scope of the problem and issues of adherence to oral antineoplastic agents.*

DATA SOURCES: *Research-based and other articles, newsletters, and conference presentations.*

CONCLUSION: *Suboptimal adherence to oral antineoplastic agents is a significant clinical problem that may result in disease or treatment complications, adjustment in treatment regimen, disease progression, and premature death.*

IMPLICATIONS FOR NURSING PRACTICE: *Healthcare providers need to monitor and facilitate adherence by identifying barriers and implementing strategies to assure adherence, and therefore, improve clinical outcomes.*

KEY WORDS: *Cancer, oral agents, antineoplastic, adherence, scope of problems*

RECENT progress in the treatment of cancer has seen an accelerated use of oral antineoplastic agents. At this time, nearly 50 oral antineoplastic agents are approved for use in the United States alone,

with nearly half of all new agents in development being oral.^{1,2} This new treatment paradigm shifts delivery of intravenous (IV) chemotherapy from a safe, controlled process monitored on a regular basis by oncologists and oncology nurses in

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hospitals or outpatient clinics, to patients' homes where the complexity of knowing dosing, side effects, and toxicities becomes responsibility of the patient and family. The dosing regimens are often complex, and even for the most medically sophisticated patient and family, responsibilities for monitoring and taking medications, and then managing symptoms, side effects, and adverse events can be overwhelming.² The problem is especially grave for cancer patients who often require long-term or lifelong therapy, because poor medication adherence leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and premature death.³ In this article, the problem, scope, and issues involved with adherence to oral antineoplastic agents are discussed.

THE DEFINITION OF ADHERENCE

There is no "gold standard" definition of adherence. However, there is a vast amount of literature examining medication adherence, most of which offer definitions.

Conceptual Definition of the Health Status Outcome Adherence

The World Health Organization defines adherence as the extent to which a person's behavior corresponds with agreed recommendations from a healthcare professional.⁴ A commonly used definition is the extent to which a person's behavior-taking medications, following a diet and/or exercising follows recommendations from a healthcare provider.⁵ A more precise definition of medication adherence was recently offered by the International Society for Pharmacoeconomics and Outcome Research (ISPOR), as "the degree or extent of conformity to the recommendations about day-to-day treatment by the provider with respect to the timing, dosage, and frequency." ISPOR extends this definition by adding persistence, which they define as "the duration of time from the initiation of the medication to discontinuation of therapy."⁶ Each of these conceptual definitions lay the foundation for measuring adherence.

Operational Definition of the Health Status Outcome Adherence

Medication adherence is routinely operationalized in the literature as a percentage of how many of the prescribed pills a patient has taken (ie, 80%, 90%, or 100%) compared with what

they were prescribed. In many instances in the literature, a patient is considered to be adherent when they have taken 80% of a prescribed medication.⁷ Often, when self-report of medication adherence is used as the measure, a yes or no (dichotomous) question is asked of the patient.^{8,9} When Medication Event Monitoring System (MEMS [electronic pill boxes that alarm and measure cap openings]) are used, the number of bottle cap openings are compared with the number of expected bottle cap openings prescribed during a treatment period.¹⁰ When pharmacy claims data are used to examine adherence, a proportion of the days that the patient had the medication available is compared with the proportion of the days that the patient had the medication prescribed over the observation period and is calculated as the percentage of adherence.¹¹ When biologic measures such as urine or serum assays are used, specific ranges of blood or urine levels are expected to be associated with adherence to a medication regimen.^{12,13} The operational definition of adherence is dependent upon which of these measures, or combination of these measures, is used to assess adherence.

Definition of Adherence Used in Research on Oral Agents

Three systematic reviews have been conducted on oral antineoplastic agents. One review of 12 studies used the most commonly cited definition of adherence in the literature, 'the extent to which a person's behavior coincides with medical or health advice',¹⁴ a second review (n = 22) used the ISPOR definition,¹⁵ while the third (n = 6) concluded that no standard definition of adherence was used across studies and this made comparison of results between studies difficult.¹⁶ Of the 43 studies in the literature, only 24 reported a definition of adherence (see article on assessment and measurement by Given and Spoelstra elsewhere in this issue). Examples of general definitions were 90% to 100% of pills taken and/or the extent to which a person's behavior coincides with medical or health advice. Specific definitions included 100% adherence for taking medication at correct date or time, or the prescribed number of doses taken based on pill count and MEMS, within 2 hours of prescribed dosing interval and with the correct number on day of treatment.¹⁷ Definitions of adherence are more precise and measurable in the more recent oral antineoplastic agent studies.

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