

Oral Agents

Challenges with self-administered medication adherence in clinical trials

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BACKGROUND: In oral agent clinical trials, patients may not be adherent to self-administration of study medication; this nonadherence can affect validity and reliability. Many factors contribute to nonadherence to protocol requirements, and managing patients with fidelity issues is the responsibility of the research team.

OBJECTIVES: The aim is to identify which group (patients, physicians/principal investigators, nurses, or other personnel) research nurses report as most responsible for protocol nonadherence and to characterize the most observed causes and contributors to nonadherence within each group.

METHODS: Sixty-seven protocol nurses completed a nine-question survey developed from pilot data. Descriptive statistics and ordinal regressions addressed the objectives of the study.

FINDINGS: More than half of the nurses observed clinical trial nonadherence in their practices. Nurses identified challenges regarding physician, patient, and nurse factors. The most frequently identified causes included patients' forgetfulness, refusal to undergo study procedures, inadequate family or caregiver support to complete study activities, ineffective communication, and collaboration within the research team.

AS OF MAY 2018, MORE THAN 272,000 CLINICAL TRIAL STUDIES EXIST, with more than 5,500 trials investigating oncolytic agents (ClinicalTrials.gov, 2018). Adherence to procedures in cancer clinical trials is essential to the validity of outcomes. Although extensive efforts are made to ensure that each clinical trial adheres to the study procedure, breaks in study protocols are not uncommon. The rates of protocol violations are difficult to fully ascertain because they are not commonly reported in the literature (Sweetman & Doig, 2011). Post-marketing studies completed for the U.S. Food and Drug Administration (FDA) indicated that 15%–24% of trials contained protocol violations, but that finding was based on a narrow definition of nonadherence (Dodd, White, & Williamson, 2012; Macias et al., 2004; Sprung, Finch, Thijs, & Glauser, 1996). The complexities of clinical trials, the number of clinicians involved, and a variety of patient and environmental issues contribute to protocol violations. A dearth of knowledge exists about the rates and sources of protocol violations observed by research nurses.

The expansion of oral agent trials has increased the risk of patient-based nonadherence because dose administration is probably a patient's responsibility outside the healthcare setting. Unobserved patients are more likely to not adhere than those who are observed or administered study drugs (Agoritsas, Deom, & Perneger, 2011). Invariably, this will affect the quality of the data reported to establish drug efficacy and render judgment on clinical significance. With nonadherence to study medication and requirements of the protocol, the integrity of the data becomes questionable and the validity and reliability of the study potentially compromised. Clinical trial nurses are in a unique position to provide insight into common sources of protocol violations. The current study characterized groups and sources responsible for protocol breaks as a first step in seeking to mitigate them.

Background

Clinical Trials

Clinical trials are recommended for patients with cancer; however, such trials are not recognized as the standard of care but a method of comparison with standard of care treatment in determining effectiveness (Weingart et al., 2008). Complex and rigid protocol designs may discourage potential candidates from participating in a study. Protocols can be confusing and difficult to understand, leading to nonadherence by the participants enrolled in the study. Members of the healthcare team also can be responsible for nonadherence because of confusing protocols (McCue, Lohr & Pick, 2014). In a

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adherence; oral agents; protocol; research; assessment; patient-reported outcomes

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