Clinical Trials and Communicating Safely

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In the arena of clinical trials, patient safety is of the highest concern. Despite rules and regulations to protect participants, errors still occur. Deviations from standard practice, complexity, and unfamiliarity all may contribute to errors that occur in the research setting. Detailed and precise communication must exist between the research team and clinical staff to maintain patient safety and protocol integrity.

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Human subjects are central to the clinical trial endeavor. Great importance must be placed on respecting and protecting the safety and rights of human research participants (Fedor & Gabriele, 2006; McDonald, 2009). A rigorous review and oversight process is mandated to assure protection of research participants (American Society of Clinical Oncology, 2009). Sadly, those rules and regulations are a direct result of past abuses of patients participating in research studies. Despite protections, errors that impact patient safety still occur. The research team is responsible for protecting the rights and safety of those enrolled. Simply having rules and regulations is not enough; all individuals involved in the research process must adhere to them (Hanna, 2002). The research nurse plays a central role in the coordination of patient care, as well as the development and establishment of trust with the patient and the research team (McDonald, 2009). Proper and timely communication is essential to establishing trust, assuring integrity, and protecting the patient.

Communication Errors

Poor communication is the single most frequent cause of adverse events across all facets of health care (Lingard et al., 2008). The Joint Commission (2011) reported that communication errors are a major root cause of sentinel events, ranking among the top three in virtually all categories. Those errors may be related to patient handoff procedures, poor handwriting, the physical setting, and even organizational hierarchy. Although the literature does not specifically discuss those errors in the context of clinical trials, good communication is critical in any intervention that involves more people, increases the cognitive load, or strays from standard practice (Lingard et al., 2004; Wood, 2006).

The culture and diversity within an institution also may interfere with effective team communication. Team members may have different cultural backgrounds, training, and viewpoints, which all contribute to the interpretation of a given message. In a hierarchical atmosphere, staff may be uncertain or anxious to ask questions or convey important information (Marshall, Harrison, & Flanagan, 2009). The research nurse and the principal investigator must be cognizant and accommodate different interactive styles, as well as foster an atmosphere of approachability. Sharing important information and safety concerns is not only important to protect an individual patient, but to protect all patients who participate in the study.

Lindgard et al. (2004) studied the characteristics of communication failures and classified them into four types: occasion, content, audience, and purpose. Occasion refers to the timing of the information exchange and was the most common type of failure noted—occurring when information is given at an inappropriate time. In addition, content is when information is missing or incorrect; audience refers to when a key team member is left out of the communication loop; and purpose describes situations where the goal of the communication is unclear, not achieved, or inappropriate. Each one of those failures can arise within the clinical trial setting. For example, providing the list of pretreatment laboratory results to the nurse after the treatment has begun would be an occasion failure. An audience failure would occur when the research nurse reviews the protocol treatment plan with the investigator and the pharmacist without the treatment nurse present. Providing the wrong time for a blood draw would be a content failure. An effective clinical trials communication system ensures that information is clear, timely, complete, and all key team members are included.

Multidisciplinary Care

Patients with cancer often require care from multiple health professionals in a variety of settings (Aubin et al., 2010). Healthcare systems typically are not designed with the demands of research in mind. Research usually involves multiple complex requirements that vary from standard practice (Davenport, 2010; Iesue-Queen, 2008). Deviating from standard practice, complexity, and unfamiliarity may contribute to errors that occur