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.

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.

Lingard 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; Issue-Queen, 2008). Deviating from standard practice, complexity, and unfamiliarity may contribute to errors that occur.
in the research setting. Those errors not only affect the safety of the patient, but also the outcomes and validity of the study. Errors in communicating can contribute to safety issues when the intervention finally comes to market. Detailed and precise communication must exist between the sponsor, research team, and clinical staff to maintain patient safety and protocol integrity (Ward, Castro, & Jones, 2009).

The research team is comprised of all individuals who provide any protocol-required care to a patient participating in a clinical trial. The principal investigator, research coordinator, data manager, and regulatory personnel generally are referred to as the research team; however, other healthcare professionals also contribute vital information to the study (see Figure 1). The head of the team is the principal investigator, who assumes all responsibility for the team and their actions. The principal investigator is responsible for ensuring that everyone is qualified by knowledge and expertise to conduct their part of the study. The study coordinator, or research nurse, coordinates all the aspects of patients’ care on study. Effective teamwork is linked to improved patient outcomes and patient safety (Brown & Freeman, 2009). Communication between all members of the team is essential to the safety of the patient, which sometimes supersedes the study.

The research protocol is the document that outlines the study design and treatment plan. It can be thought of as a recipe that is followed to ensure that all patients, regardless of location, are treated safely and in the same fashion. The principal investigator and the research nurse serve as content experts of that document and they are responsible for communicating the protocol requirements to the multidisciplinary team. Effective communication can make the difference between an optimal outcome and an adverse outcome (Risk Insurance Company Risk Management Foundation, n.d.).

Improving Communication in Clinical Trials

Communication is the process in which participants create and share information with one another to reach a mutual understanding. Two or more individuals exchange information to move toward each other in the meanings that they give to certain events. That model can be applied to develop a system to disseminate protocol information to the research team.

Understanding the current channels of communication is imperative, as is understanding the social interaction within an organization prior to imparting new information to a multidisciplinary team. First, the members of the research team should be identified, including anyone who will conduct any part of the protocol intervention. Second, the communication patterns that the team currently uses should be identified. Although introducing new information may require time up front between team members, it ultimately will achieve clarity of purpose and enhanced understanding (Wood, 2006).

Once the team is identified and the social system is understood, the next step is to develop a standard framework for communicating information. Many hospital systems have adopted principles of communication from the aviation sector’s Crew Resource Management procedure, which is based on communicating proactively with complete and accurate information to all team members to achieve specific and shared goals (Helmreich, 2000). That framework frequently uses the acronym SBAR (which stands for situation, background, assessment, and recommendation) to assure accurate information is exchanged during patient handoff. Figure 2 provides examples of the type of clinical trial information that could be exchanged using SBAR.

With SBAR, structured tools can be developed to ensure that accurate information is disseminated to all members of the team. Many institutions have developed various checklists, fast fact sheets, or calendars to help standardize and disseminate protocol information. Information that needs to be communicated is identified and included in the checklist or tool. That helps ensure that pertinent information is exchanged with each encounter. New strategies can be evaluated using measurable outcomes, and focused

FIGURE 1. Communication in the Research Team

CRA—clinical research associate

Note. Supportive staff members include, but are not limited to, dietitians, social workers, homecare nurses, medical assistants, and scheduling personnel.
training conducted to ensure that the strategy improves the transfer of clinical information (Seago, 2008). As protocols are revised and updated, tool usage needs to be reviewed to ensure appropriate information still is being communicated.

Ward et al. (2009) described a system of communication developed at the National Institute of Health to standardize communication between the research team and the oncology clinical research nurse. The Protocol Impact Query System (PIQS) assesses and mobilizes resources to implement new clinical trials. When a new protocol is approved by the institutional review board, the research nurse completes an impact query form that outlines the patient population, phase of study, and treatment plan. That form then is reviewed to assess if the study is appropriate for the ambulatory setting and if adequate resources are available. Any potential barriers to protocol implementation also are addressed. An educational session then is scheduled for nursing staff, including an opportunity to ask and respond to questions. PIQS allows for identification of special training or clarification needed within a research team and is an example of standardized communication within the clinical trials setting.

PIQS is one example of how to proactively identify important information to convey to the research team. Each situation needs to identify a mechanism that works within their own framework. Many different types of investigative sites exist—not a one-size-fits-all approach. Many sites have a protocol review committee that does a review prior to submission to the institutional review board. At the very least, protocols should be reviewed by the research nurse and principal investigator prior to institutional review board submission. That will ensure that resources are available and conducting the study at the site will be feasible. The research nurse also should identify any special training that is needed and develop a standardized approach for communicating the information that will be necessary within the work setting.

Conclusion

The importance of effective communication in the clinical trial setting cannot be overstated. Treating patients on clinical trials typically involves additional personnel, complex information, and deviations from standard practice, all of which can contribute to patient safety issues. Using a standard approach to communicate patient and protocol information to the research team can decrease the possibility of safety issues related to miscommunication. The research team must follow the highest standards of professionalism, and always place the interests and safety of the patient above all other considerations (Koski, 2008).

References


