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The use of high-fidelity human patient simulation as an evaluative tool in the development of clinical research protocols and procedures

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Abstract

Errors in clinical research can be costly, in terms of patient safety, data integrity, and data collection. Data inaccuracy in early subjects of a clinical study may be associated with problems in the design of the protocol, procedures, and data collection tools. High-fidelity patient simulation centers provide an ideal environment to apply human-centered design to clinical trial development. A draft of a complex clinical protocol was designed, evaluated and modified using a high-fidelity human patient simulator in the Duke University Human Simulation and Patient Safety Center. The process included walk-throughs, detailed modifications of the protocol and development of procedural aids. Training of monitors and coordinators provided an opportunity for observation of performance that was used to identify further improvements to the protocol. Evaluative steps were used to design the research protocol and procedures. Iterative modifications were made to the protocol and data collection tools. The success in use of human simulation in the preparation of a complex clinical drug trial suggests the benefits of human patient simulation extend beyond training and medical equipment evaluation. Human patient simulation can provide a context for informal expert evaluation of clinical protocol design and for formal "rehearsal" to evaluate the efficacy of procedures and support tools.

Keywords: Simulation; Clinical research; Clinical trials; User centered design; Human-centered design; Human factors

1. Background

1.1. Errors in clinical research

The safe and accurate conduct of clinical trials is critical to the advancement of medical care. The time and effort spent in clinical trial research are substantial, accounting for more than six billion dollars each year

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[1]. In addition, the complexity of today's clinical trials far exceeds those of the past [2]. Failure to adhere to clinical protocols can lead to data inaccuracy or worse, significant patient injury. Data inaccuracy in the early phase of clinical trials is a commonly known, but incompletely described component of clinical research. However, little attention has been paid to optimizing human performance in the conduct of clinical research.

In informal interviews of five clinical trial researchers by the authors (JT, MW), all five researchers acknowledged the problem of early trial errors and data inaccuracy. Common problems described by the three principal investigators and two data managers interviewed are listed in Table 1. Although researchers anecdotally acknowledge these problems, very little research has been published on this issue. One exception is the research by Wolf and Makuch [3] that identified a number of potential problems in the conduct of cancer clinical trials that may affect the collection and quality of data. They suggest that identification of errors early in clinical trials can help point out problems with the protocol design that are likely to affect investigators and trial coordinators' compliance.

There are two possible contributors to problems of errors in early clinical trial data collection. The first is the experience level and quality of training of the research coordinators. While research coordinators generally have some medical training (such as nursing), any given group conducting a specific clinical trial is likely to have a wide variety of type and degree of experience. In addition, training of research coordinators usually involves some combination of home study of protocol materials and investigator meetings that use traditional didactic teaching methods such as lectures. Some research coordinators may be overconfident in their understanding of the protocol requirements and thus review materials only superficially. They may have expectations that the procedures included in the trial will be based on familiar or standard procedures, which often is not the case. As a possible solution to these training problems, Taekman et al. [4] used active learning techniques to train coordinators by having them perform the trial procedures within a realistic simulated clinical environment using a high-fidelity patient simulator. This training resulted in significant increases in coordinator confidence, beyond the confidence levels achieved through home study and participation in the investigators' meeting.

The second contributor to errors in early clinical trials is the design of protocol and data collection tools. Many of the problems in early data collection that are attributed to coordinators' inexperience or lack of training may also be the result of a failure to account for human capabilities and limitations in the design of the protocol, procedures, and data collection tools. For example, principal investigators may have unrealistic expectations regarding the experience, capabilities, and basic understanding of the research coordinators. Principal investigators who have spent a great deal of time studying a specific problem are likely to have a different mental model of the problem or protocol than research coordinators who have had limited exposure. Principal investigators tend to be more focused

Table 1
Common errors in clinical trials

1) Variability or errors in interpretation of protocol
   a) Vague definitions within the protocol (e.g., failure to define the precision required)
   b) Vague definitions in terms of screening and inclusion/exclusion criteria
   c) Variability in the tools created for protocol flow (some coordinators create their own flow sheets, others may modify sheets provided by the principal investigator)
2) Complexity of protocol for the coordinator, failure to follow the protocol
   a) Problems with coordinating multiple activities (workload problems)
   b) Difficulty monitoring timing, reliance on memory
   c) Following standard procedures instead of protocol procedures
3) Problems with monitoring and data management
   a) Difficulties with remote monitoring
   b) Requirements to query unexpected data
   c) Poor documentation of exceptions by coordinators
4) Training issues
   a) Interpretation of protocol (see #1)
   b) High coordinator turnover
5) Subject retention