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A Quality Improvement Initiative to Improve Parental Understanding of Clinical Trial Consents

PURPOSE

The purpose of the quality improvement project, known as *Face Time*, was to implement a systematic approach to the education of parents regarding clinical trial elements, in addition to the information provided at the time of clinical trial consent. Parents who consented their child to an investigational cancer therapy at a cancer treatment center expressed the need for additional education, as the complex language, excessive detail of consent forms and stress of an impending treatment process may confuse rather than enhance patients' understanding, and parents may not fully understand implications of trial participation.

METHODOLOGY

The process improvement involved an Advanced Practice Nurse (APN) asking six specific questions of the parent to determine their understanding and knowledge of clinical trial concepts (pre-test). The APN listened to each question

individually, transcribed parent responses, and identified any knowledge gaps. The APN then dialogued with the parent(s) in an educational session to address any misperceptions or concerns that were identified. A follow up session (post-test) was completed up to two weeks following the education intervention to re-assess the parent's knowledge regarding the trial. The pre and post-test questions were based on the Verbalization of Informed Consent Essentials designed for use within the consent process.

RESULTS

During the first six months of this initiative's implementation, the percentage of parents who answered questions correctly, which meant that the parents understood the specifics of clinical trial specifics, increased from 44% to 94%. This exceeded the goal of a 20% increase in the parental knowledge score. The increase

in parental knowledge score was statistically significant ($p=0.008$).

IMPLICATIONS

The majority of parents involved in this pilot program reported that the structured conversation provided increased knowledge about their child's treatment and care related to the clinical trial. Moreover, the project created a process to ensure that issues and information relevant to the clinical trial in which their child was participating were described in a standardized way with each parent. *Face Time* has important implications for the clinical trial process, as the communication between APN and parent was an effective and inexpensive way to improve the quality of care for families.