EVALUATION OF THE LITERACY DEMAND FOR SELF-REPORTED ADVERSE EVENTS DURING CHILDHOOD CANCER THERAPY

Janice S. Withycombe[1], PhD, RN, MN, CCRP; Molly McFatrich[2], MPH; Bryce B. Reeve[3], PhD; Justin N. Baker[4], MD, FAAP;
David R. Freyer[5], DO, MS; Jennifer W. Mack[6], MD, MPH; Diana Palma[5], BS, CCRP; Lillian Sung[7], MD, PhD; *Pamela S. Hinds[8], PhD, RN, FAAN
Corresponding Author: Janice S. Withycombe, PhD, RN; Email: jwithycombe@emory.edu; * Project Mentor

Background

The reporting of adverse events (AE) for those enrolled on clinical trials is mandated by the federal government. Historically, healthcare staff have completed AE reporting for children treated on oncology trials. A new instrument, the Pediatric Patient-Reported Outcome Common Terminology Criteria for Adverse Events (Pediatric PRO-CTCAE), is now in development which will allow children (and their proxies) to self-report symptomatic AEs to their healthcare providers.

The purpose of this study was to conduct and evaluate literacy assessments in conjunction with cognitive interviews in children 7 to 20 years of age and their caregiver-proxies to analyze the PRO-CTCAE measures in relationship to reading levels.

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Methods

In this multi-site study, children and their guardians were invited to participate in a cognitive interview. Sessions consisted of completing a written survey asking about specific AEs experienced by the child within the past 7 days. Participants were asked to identify "hard to understand" items. A cognitive interview session probed the understanding of the survey content. Lastly, a Wide Range Achievement Test (WRAT) was administered to score individual reading levels.

Demographics

Children Completing WRAT (n= 123)	Percentage
Female	54 %
Male	46%
Caucasian	61%
African American	21%
Asian	10%
Other	8%

Results

To date, 129 children and 112 proxies have completed cognitive interviews. Of these, 123 children and 107 proxies also completed WRAT assessments.

Child's Age (in years)	Number of WRAT Assessments	Percent below Grade Level
7	11	27% (n=3)
8	16	6% (n=1)
9-12	35	20% (n=7)
13-15	35	46% (n=16)
16-20	26	65% (n=17)

82% of 7 year olds and 13% of 8 year olds requested that the questionnaire be partially or fully read to them. Children and adolescents, ages 9-20, were generally able to independently complete the written survey (reading level mean = 8th grade for this age group). The majority of adult participants reported that the Proxy PRO-CTCAE instrument was "easy or very easy" to use.

Conclusions

Although age is commonly used as an indicator for when children should begin self-reporting their health status (with the recommended age varying from 5-8 years) our findings indicate age alone may be insufficient. Additional assessments are planned for children (ages 7-9) to further evaluate reading ability related to the Pediatric PRO-CTCAE. Older children were more likely to have reading levels below their age/grade level, but had greater ability to independently complete the Pediatric PRO-CTCAE questionnaire.

Author Affiliations

1- Emory University Nell Hodgson Woodruff School of Nursing, Atlanta, GA; 2 - UNC Lineberger Comprehensive Cancer Center, Chapel Hill, NC; 3 - University of North Carolina, Chapel Hill, NC; 4 - St. Jude Children's Research Hospital, Memphis, TN; 5 - Children's Hospital Los Angeles, CA; 6 - Dana-Farber Cancer Institute/Boston Children's Hospital, Boston, MA; 7 - The Hospital for Sick Children, Toronto, ON; 8 - Children's National Health System, Washington, District of Columbia