Examining Differences in Opportunity and Eligibility for Cancer Clinical Trial Participation Based on Sociodemographic and Disease Characteristics

Jessica Rearden, PhD, RN, Alexandra L. Hanlon, PhD, Connie Ulrich, PhD, RN, FAAN, Margo Brooks-Carthon, PhD, CRNP, and Marilyn Sommers, PhD, RN, FAAN

Rearden is the Ruth L. Kirschstein T32 postdoctoral fellow, Hanlon is a research professor, Ulrich is an associate professor of bioethics, Brooks-Carthon is an assistant professor, and Sommers is the Lillian S. Brunner professor of medical-surgical nursing, all in the School of Nursing at the University of Pennsylvania in Philadelphia.

This research was supported by an NINR F31 Individual Predoctoral Fellowship (1F31NR01407601A1), the Ruth L. Kirschstein T32 predoctoral fellowship (T32NR00710017; Pl: Sommers), and the American Nurses Foundation/Council for the Advancement of Nursing Science.

Rearden, Hanlon, Ulrich, Brooks-Carthon, and Sommers contributed to the conceptualization and design, analysis, and manuscript preparation. Rearden completed the data collection. Hanlon provided statistical support.

Rearden can be reached at genewskj@ nursing.upenn.edu, with copy to editor at ONFEditor@ons.org.

Submitted March 2015. Accepted for publication May 12, 2015.

Key words: cancer clinical trial; opportunity; eligibility; under-represented groups

ONF, 43(1), 57-66.

doi: 10.1188/16.0NF.57-66

Purpose/Objectives: To examine differences in opportunity and eligibility for cancer clinical trial (CCT) participation based on sociodemographic and disease characteristics.

Design: A matched cross-sectional study including a prospective oral questionnaire and retrospective electronic medical record (EMR) review.

Setting: A single hospital in a large academic National Cancer Institute-designated cancer center in Philadelphia, Pennsylvania.

Sample: 44 Black or Hispanic and 44 Non-Hispanic White newly diagnosed individuals matched on cancer type and age (plus or minus five years).

Methods: Participants answered a questionnaire to capture self-reported opportunity for CCT participation, sociodemographic information, and cancer type. With consent, the authors completed a retrospective review of the EMR to assess eligibility and collect cancer stage and performance status.

Main Research Variables: Opportunity and eligibility for CCT participation.

Findings: Most participants (78%) had no opportunity for participation and were ineligible for all available trials. No differences were noted in opportunity for participation or eligibility based on race or ethnicity. Participants with late-stage disease were more likely to have opportunity and be eligible for CCT participation (p = 0.001). Those with private insurance were less likely to have opportunity for participation (p = 0.005).

Conclusions: Limited trial availability and ineligibility negatively influenced opportunity for CCT participation for all populations. Levels of under-representation for CCT participation likely vary within and across sociodemographic and disease characteristics, as well as across healthcare settings.

Implications for Nursing: The unique roles of nurse navigators and advanced practice nurses can be leveraged to increase opportunities for CCT participation for all populations.

acial and ethnic minority populations, older adults, and the economically disadvantaged are significantly under-represented as cancer clinical trial (CCT) participants (Murthy, Krumholz, & Gross, 2004; Sateren et al., 2002). Inequitable participation in CCTs decreases the generalizability of results and diminishes the chance for under-represented groups to receive new and potentially life-saving treatments. A large portion of literature on under-representation identifies patient attitudes as a barrier to CCT participation, but evidence challenges this view (Comis, Miller, Aldige, Krebs, & Stoval, 2003; Langford et al., 2014; Markman, Petersen, & Montgomery, 2008; Mohd Noor et al., 2013; Wallington et al., 2012; Wendler et al., 2006). Research suggests that under-represented groups are just as willing to participate in clinical trials as well-represented groups but receive fewer opportunities for participation (Wendler et al., 2006). Opportunity for participation is defined as an offer for screening and/or enrollment in a CCT from a healthcare provider or