

Title:

Impact of Health Literacy on Clinical Trial Enrollment for Breast Cancer Patients

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Session Title:

Global Concerns for Cancer Clinical Trials

Slot:

O 10: Sunday, 30 July 2017: 1:15 PM-2:00 PM

Scheduled Time:

1:35 PM

Keywords:

breast oncology, clinical trials and health literacy

References:

DeWalt, D., Berkman, N., Sheridan, S., Lohr, K., & Pignone, M. (2004). Literacy and Health Outcomes: A Systematic Review of the Literature. *Journal of General Internal Medicine*, *19*, 1228–1239.

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Krieger, J. L., Neil, J. M., Strelakova, Y. A., & Sarge, M. A. (2017). Linguistic Strategies for Improving Informed Consent in Clinical Trials Among Low Health Literacy Patients. *Journal of the National Cancer Institute*, *109*(3), djw233. <http://doi.org/10.1093/jnci/djw233>

Nielsen-Bohlman, L., Panzer, A. M., Hamlin, B., & Kindig, D. A. (n.d.). Health Literacy A Prescription to End Confusion.

Sarkar, U., Schillinger, D., López, A., & Sudore, R. (2011). Validation of self-reported health literacy questions among diverse English and Spanish-speaking populations. *Journal of General Internal Medicine*, *26*(3), 265–71. <http://doi.org/10.1007/s11606-010-1552-1>

Wolf, M. S., Williams, M. V, Parker, R. M., Parikh, N. S., Nowlan, A. W., & Baker, D. W. (2007). Patients' shame and attitudes toward discussing the results of literacy screening. *Journal of Health Communication*, *12*(8), 721–32. <http://doi.org/10.1080/10810730701672173>

Abstract Summary:

Health literacy has been understudied in the cancer population, and there is limited evidence about the relationship of health literacy to enrollment in cancer clinical trials. This presentation will highlight

research focused on the relationship between health literacy and clinical trial enrollment in a breast cancer population.

Learning Activity:

LEARNING OBJECTIVES	EXPANDED CONTENT OUTLINE
Learner will examine the importance of health literacy in cancer navigation.	The presentation will describe the relationship of health literacy to pertinent clinical outcomes while highlighting the underrepresentation of health literacy in cancer research, and in particular on research assessing enrollment in clinical trials.
Learner will be able to explore patient-related factors that are related to limited health literacy and explore the relationship between health literacy and clinical trial enrollment.	Pertinent statistical relationships will be presented from an breast oncology clinic at an academic institution in the United States, but aspects are translatable to other cancer types and international settings.

Abstract Text:

Purpose:

Health literacy, or the ability to obtain, appraise and integrate health-related knowledge, is recognized by the Institute of Medicine as an integral component of high-quality health care. In adults, limited health literacy can be a critical indicator of adverse health outcomes such as: diminished health-related knowledge, increased measures of morbidity, poor adherence to medication regimens, and high utilization of health care resources. It is estimated that 20 - 36% of all adults in the United States have limited health literacy, and that the prevalence rises to closer to 50% among those who are also from a low income background. DeWalt and colleagues have demonstrated that adult patients with limited health literacy are less likely to participate in shared medical decision-making and adults with limited health literacy are more likely to experience shame, low self-esteem, and limited social support. With a renewed focus on patient-centered approaches, limited health literacy can diminish patient engagement in care and autonomy in self-care management.

Health literacy has been understudied in cancer, where patients must navigate difficult health care decisions and self-care management. Therapeutic clinical trials remain a predominant aspect of cancer care delivery and is the gold standard for developing new medical treatments and translating biomedical discoveries. A key barrier to participation in clinical trials is the process of randomization, and how the treatment and side effects of the treatment are explained during the clinical trial consent process and very little previous research has focused on health literacy as a critical component of this process. Therefore, the purpose of this prospective correlational study was to determine if patient's level of health literacy predicts the decision to enroll in a clinical trial among breast cancer patients.

Methods:

From June 2015 through September 2016 a health literacy questionnaire was administered to all new breast cancer patients and all breast cancer patients seen in follow-up. The health literacy questionnaire is a valid and reliable 3-item self-report screening tool with ranges in score from 3-15 (higher scores represents lower health literacy). Pertinent clinical outcomes related to the diagnosis and treatment was obtained for all patients with a health known health literacy score. Enrollment of a clinical trial was designated as a yes/no dichotomous outcome variable and included chemotherapy, radiation, and

surgical clinical trials pertinent to the breast cancer diagnosis. Descriptive statistics were calculated to describe health literacy and patient characteristics, and a multivariate logistic regression was calculated to determine the relationship of health literacy on decision to enroll in a clinical trial.

Results:

512 breast cancer patients were included in this analysis. Among these women, 12.1% of the patients were identified as having the lowest level of health literacy (limited health literacy) and 13.5% were identified as having marginal health literacy. 12.9% of the study population were enrolled in a clinical trial (n=66). In logistic regression, there was no statistical significance in the relationship between health literacy and enrollment in a clinical trial ($p = 0.09$).

Conclusion:

Health literacy is not well defined in the breast cancer patient population and the health literacy-specific aspects of the clinical trial informed consent process have been understudied. Our findings did not demonstrate a relationship between health literacy and enrollment in a clinical trial. One limitation to our findings was that chemotherapy, radiation and surgical clinical trials were included in the same outcome variable. Each of those clinical trials has various risk/benefit profiles and future study is warranted investigating the relationship of health literacy to individual trial types. Nurses play a key role in understanding a patient's health literacy and offering tailored educational and shared decision-making support.