
Impact of health literacy on clinical trial enrollment for breast cancer patients



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Overview

- Health literacy has been understudied in the cancer population
- Limited evidence thus far on the impact of health literacy and clinical trial enrollment
- Presentation highlights relationship between health literacy and clinical trial enrollment in a single breast cancer clinic population (Virginia, USA)

What is health literacy (HL)?

- Health literacy, or the ability to obtain, appraise and integrate health-related knowledge, is recognized by the Institute of Medicine (IOM) as an integral component of high-quality health care.
- Estimated prevalence (20-36%) in US samples

Association between HL and health outcomes

- Adults with limited health literacy are less likely to participate in shared medical decision-making, more likely to experience shame, low-self-esteem, limited social support.
 - Less likely to adhere to medications or attend medical appointments.

HL and cancer

- Understudied in cancer; must navigate difficult health decisions and engage in self-care management.
 - Current knowledge re: HL and cancer centers on screening (mammogram, etc.)
- Therapeutic clinical trials remain a predominant aspect of cancer care delivery.
- A key barrier to participation in clinical trials is understanding the process of randomization, clinical equipoise, and treatment side effects.
 - Consent process

Study purpose

- The purpose of this 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.

HL assessment

- 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) (Sarkar, Schillinger, López, & Sudore, 2011).
- (1) How confident are you in filling out medical forms?, (2) How often do you have problems learning about your medical condition(s) because of difficulty understanding written information?, and (3) How often do you have someone help you read hospital materials?
- 9+ = limited health literacy; 7-8 = marginal health literacy, therefore **7-15 = low health literacy**

HL assessment in health record

Report ? Close X

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Performs self breast exam: Monthly
Date of last GYN exam: March 2015

Health Literacy Screen

Item	Assessment	Score
Patient's confidence in filling out medical forms	1 = extremely	1
How often does patient state they have problems learning and understanding written information regarding their medical condition(s)?	3 = sometimes	3
How often does patient state they have someone help them read hospital materials?	3 = sometimes	3

TOTAL SCORE: 7

Methods

- From June 2015 through September 2016 we administered a HL questionnaire to all new breast cancer patients and previously treated breast cancer patients seen in follow-up
- 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.

Analysis

- 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
- 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 ($p = 0.09$).

Discussion

- Our findings did not demonstrate a relationship between health literacy and enrollment in a clinical trial.
- Confounder: type of clinical trials available (example: intra-operative radiation therapy)
- Nurses play a key role in understanding a patient's health literacy and offering tailored educational and shared decision-making support.

Limitations

- Single academic clinic sample
- Chemotherapy, radiation-therapy and surgical clinical trials were treated as same outcome variable.
 - Each has various risk/benefit profiles

Future steps

- Information seeking/appraisal regarding clinical trials
 - eHealth literacy
- Consent processes for those with limited health literacy
- Stigma, lack of trust
- Adherence to clinical trial protocol (i.e., oral medications)

Citations relevant to this study:

- (1) Keim-Malpass, J, Doede, A, Camacho, TF, Kennedy, C, Showalter, S. Impact of patient health literacy on surgical treatment of breast cancer. In press at: The Breast Journal
- (2) Keim-Malpass, J, Doede, A, Kennedy, C, Showalter, SL. (2017). Health literacy assessment: Feasibility in a breast surgical oncology clinic. *Clinical Journal of Oncology Nursing*, 21(3), 384-386. Doi: 10.1188/17.CJON.384-386

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