



A novel clinical trial recruitment strategy for women's cancer



B.J. Rimel^{*}, Jenny Lester, Leah Sabacan, Diane Park, Catherine Bresee, Catherine Dang, Beth Karlan

Cedars-Sinai Medical Center, 8700 Beverly Blvd, Los Angeles, CA 90048, United States

HIGHLIGHTS

- An online patient-facing registry improved accrual over a paper based registry.
- Online registry participants matched to studies faster than paper based participants
- Fifteen percent of women who participated in the registry enrolled in clinical trials

ARTICLE INFO

Article history:

Received 25 January 2015

Accepted 13 May 2015

Available online 20 May 2015

Keywords:

Clinical trial

Registry

Enrollment

ABSTRACT

Objective. To address a deficiency in clinical trial and research enrollment in gynecologic cancer studies, we launched a paper based patient research registry. To improve registry enrollment, we transitioned to an online registry and trial matching mechanism to aid women in accessing open studies.

Methods. Utilizing a validated verification platform, we designed a web-based registry and trial matching mechanism for women over age 18. Participants completed a questionnaire to provide information for trial matching. A focus group of registry participants was held 9 months after the start of the study to evaluate barriers to participation.

Results. A total of 322 women were enrolled in the online registry over a 14 month period which was a 4.3 fold increase over the paper-based registry ($p < 0.0001$). Two hundred and sixty three (82%) women were matched to at least one study. Fifteen percent (39/263) of those eligible for studies went on to enroll. The online enrollment rate to studies was not different from that observed in the paper-based registry (26/172, $p = 0.934$), however, the web-based registry linked participants to subsequent studies 27% more rapidly (68 (+/− 98) days vs. 93 (+/− 81) days for the paper-based registry, $p = 0.017$). Focus group participants identified areas for improvement.

Conclusion. Web-based patient driven registry provides dramatic improvement in the number of participants enrolled and the time to trial linkage compared to a paper based registry at a single institution. Further studies of barriers to research participation are necessary to improve on this model.

© 2015 Elsevier Inc. All rights reserved.

1. Introduction

Less than 2% of patients with cancer participate in a clinical trial in the United States [1]. Gynecologic oncology patients do not appear to participate in trials with any more frequently than other cancer types. While gains in progression free survival have continued to improve overall life span for women with advanced gynecologic cancers, more cures have not been realized. Lack of accrual to trials leads to early closure of studies and a waste of critical resources as well as extended periods of enrollment which can hinder the ability to interpret the results. Stensland et al. reported that 1 in 4 cancer clinical trials were

stopped early with 1 in 10 being stopped for poor accrual [2]. Data are somewhat limited, but a panel of experts convened by the NCI and ASCO to discuss barriers to clinical trial enrollment in 2013 [3] cited barriers in three areas as most significant: 1) patient/community – 2) physician/provider level – 3) site/organizational. Physician/provider level barriers include willingness to refer a patient for study, lack of knowledge about available clinical trials and concern regarding a patient's ability to participate [3–5]. Patient/community barriers have been noted to include being unaware of trial opportunities and complexity and stringency of the protocol [6] Both of these barriers could be addressed by providing a research registry to inform and match patients for study.

Clinical trials, defined by the National Institute of Health as “a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health related biomedical or behavioral outcomes”

^{*} Corresponding author at: Cedars-Sinai Medical Center, 8700 Beverly Blvd Suite 290W, Los Angeles, CA 90048, United States. Tel.: +1 310 423 5800 (office); fax: +1 310 967 1142.

E-mail address: Bobbie.rimel@cshs.org (B.J. Rimel).

[7], are the primary focus for enrollment of most patients with an active malignancy. Clinical research studies such as tissue banks and longitudinal cohort studies provide invaluable data for researchers but require a consenting population and may be overlooked when the focus is on therapeutic intent. Non-interventional research studies related to screening, surveillance and survivorship offer opportunities for women without cancer to engage in research that may result in improved detection or risk assessment. However, these women are harder to find as they are not commonly present in the cancer centers where clinical trial recruitment and research participation are more the norm.

Recent data from the Pew Internet Research Project suggests that 86% of women use the internet and 72% of those users are accessing the internet to find medical information [8]. Similarly, 76% of women who use the internet participate in social networking sites, making the online distribution of clinical trial and research study information and recruitment possible in this population [9].

Based on the barriers to enrollment and the common utilization of digital technology in our target population, we hypothesized that a patient-facing online registry would provide greater registry participation than a previous paper based consent and registry. We also hypothesized that a computer trial matching process would improve enrollment of registry participants to clinical trials and research studies. The goal of this study was to develop an online patient driven registry utilizing a valid online consent process to connect women interested in participating in clinical research.

2. Methods

In 2010 a paper based research registry was designed to obtain epidemiologic information from female patients at a single institution. This study was approved by the institutional review board. Paper consent forms and a short demographic and medical history questionnaire were provided to female patients checking in at the imaging, breast and cancer centers. Various marketing methods were used to improve registry accrual, including posters placed in the centers, informational cards, and card-drop boxes for patients interested in being contacted in several locations and closed circuit TV ads in the hospital. Recruitment to the registry was low with an average of 5 participants enrolled per month. The paper questionnaires were then manually entered into the research database by study staff, and clinical trial matching was performed on the research database.

After noting continued low accrual despite internal marketing methods, we designed a novel online consent process utilizing a validation method that meets the federal guidelines for digital consent process (21CFR). This study was approved by the institutional review board and was initiated on March 17, 2013. Using a web-based informed consent process with a validation screen, women could chose to participate through an electronic signature that verifies that they have read the consent and are attesting that they wish to participate. The vendor used to create the email signature validation was DocuSign. Participants were given clear instructions that data security will be upheld to the highest standard, but like all other online data, could be subject to unavoidable data breach. Upon completion of the online consent process, participants were asked to complete a questionnaire with demographic, geographic, cancer history and medical history questions. The data points chosen for the questionnaire represent major inclusion and exclusion criteria for a large number of clinical trials and research studies at our institution. Once the questionnaire is completed a query of available studies that match the participant's criteria is run. Patients identify how they wish to be notified of potential study matches (by email, US postal mail, or phone call) in the questionnaire. Once a match is made, the information regarding the nature of the study and the study coordinator contact information is delivered to the participant in her chosen format. The list of available studies and the correct contact information for the study coordinator is carefully updated to ensure that the appropriate information is given to participants.

To inform potential participants of the online registry, we continued to have posters in the centers and informational cards. We also distributed the website to local ovarian cancer support communities and utilized online media outlets, and social media (Facebook posts by cancer community organizations/twitter posts) to promote the website.

Paper consents and questionnaires were still available in the clinics for women who chose not to enroll online.

Differences in observed frequencies between the web-based and traditional paper-based registry were tested using the Chi-square test or Fisher's exact test (in the case of sparse data). Continuous data are presented as means \pm standard deviation and tested by way of a Student's *t*-test. All data were analyzed with SAS v9.2 statistical software. For all statistical tests the level of significance was set at $p < 0.05$.

3. Results

A total of 507 women enrolled in the research registry from March 2010 to May 2014. Conversion to the online registry format significantly increased registry participation compared with the paper based system. The average monthly enrollment to the registry increased from 5.4 women per month with the paper based registry to 23.0 women per month with the web-based registry ($p < 0.0001$). In the first 14 months of the online registry a total of 322 women participated. We also noted demographic changes in the registry participants with the conversion to the online format. Online participants tended to be younger, were less likely to have been tested for BRCA mutation, and less likely to have a cancer. In addition, online participants were significantly more diverse, with more non-white participants (25% vs. 15%, $p < 0.001$). Demographic changes in the registry are detailed in Table 1.

In the paper based registry, 172 women were eligible for at least one study (93%) while in the online cohort, only 263 (82%) were eligible for at least one study, ($p < 0.001$). Despite the decrease in overall eligibility there was no difference in the rate women went on to enroll in another study with 15% in both the paper-based system (26/172) and the online system (39/263; $p = 0.935$). In fact, there were more total enrollments in the online cohort, 39 vs. 26, but the improvement did not reach statistical significance ($p = 0.528$). The studies that patients participated in were a hereditary cancer cohort study, an ovarian cancer screening study, an imaging study and a tissue bank study, a disease specific biobank study, and a BRCA survey and translational study. No patients

Table 1

Comparison of demographics, genetic testing and cancer types between the paper based registry and the web based registry.

	All cases (n = 507)	Paper based (n = 185)	Web based (n = 322)	P-value
Age, y (mean \pm SD)	50.4 \pm 14.0	55.8 \pm 13.1	47.2 \pm 13.6	<0.0001
Race				0.0049
White	400 (79%)	158 (85%)	242 (75%)	
Asian	39 (8%)	11 (6%)	28 (9%)	
Black	19 (4%)	9 (5%)	10 (3%)	
Latino	17 (3%)	1 (1%)	16 (5%)	
Other/Declined to state	32 (6%)	6 (3%)	26 (8%)	
Religion				0.2538
Jewish	112 (22%)	46 (25%)	66 (24%)	
Other/Declined to state	244 (48%)	139 (75%)	256 (80%)	
BRCA tested				<0.0001
Yes	143 (28%)	84 (45%)	59 (18%)	
No	332 (65%)	87 (47%)	245 (76%)	
Unknown	32 (6%)	14 (8%)	18 (6%)	
Cancer history				<0.0001
Breast	113 (22%)	81 (44%)	32 (10%)	
Gynecological	85 (17%)	17 (9%)	68 (21%)	0.0005
Other types	66 (13%)	34 (18%)	32 (10%)	0.0065
None	289 (57%)	69 (37%)	220 (68%)	<0.0001

Download English Version:

<https://daneshyari.com/en/article/3943175>

Download Persian Version:

<https://daneshyari.com/article/3943175>

[Daneshyari.com](https://daneshyari.com)