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Participant recruitment and motivation for participation in optical technology for cervical cancer screening research trials

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Abstract

In order to improve recruitment for cervical cancer screening trials, it is necessary to analyze the effectiveness of recruitment strategies used in current trials. A trial to test optical spectroscopy for the diagnosis of cervical neoplasia recruited 1000 women from the community; the trial evaluated the emerging technology against Pap smears and colposcopically directed biopsies for cervical dysplasia. We have examined women's reasons for participating as well as the effectiveness and efficiency for each recruitment strategy. Reasons for participation were identified and compared between trials. The recruitment method that resulted in the most contacts was newspaper reportorial coverage and advertising, followed by family and friends, then television news coverage. The most cost-effective method for finding eligible women who attend the research appointment is word of mouth from a family member or friend. Recommendations are given for maximizing the efficiency of recruitment for cervical cancer screening trials.

Keywords: Patient recruitment; Patient motivation; Clinical trials; Cervical screening; Cancer prevention

Background

New technology advances the mission to make cervical cancer preventable through early detection and treatment of cervical dysplasia. Evaluation of new technology requires extensive clinical trials, which provide valuable information about effectiveness, logistics, and technical troubleshooting. The new technology must be tested against the current standard of care, colposcopically directed biopsy, for validation. Participant recruitment is crucial for the execution of clinical trials; therefore, it is important to develop effective recruitment methods based on common motivations for participation. Because the clinical screening trials require many healthy participants, recruitment is challenging. Many women are reluctant, embarrassed, or fearful of current cervical cancer detection procedures. Furthermore, because the target population is made up of healthy women, they are not motivated to participate in order to ameliorate serious disease. There is abundant literature on patient recruitment for drug studies [1], palliative care studies [2], and for ongoing clinical trials [3]. Previous trials that evaluated drugs for treatment of cervical intraepithelial neoplasia (CIN) grade II or grade III revealed several important recruitment strategies: having multiple testing sites, creating a trusting relationship between potential patients, nurse practitioners and research investigators, and contacting patients multiple times [4]. Most studies of recruitment focus on patients who need some form of treatment for a health condition. There is a lack of studies on the motivation for participation and recruitment of healthy populations, such as those needed for trials of emerging technology for cervical cancer screening.

Studies on the recruitment of minority populations highlight some of the barriers to trial participation and suggest strategies for optimizing recruitment. For example, while the African American population has a 33% higher mortality rate and higher incidence for all cancers than the

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Caucasian American population [5], they have lower rates of participation in cancer clinical trials. Reasons include lack of physician participation [5], economic disadvantages [6], lack of transportation [7], and lack of information [7]. Including a representative sample of minority women for cervical cancer screening trials is imperative.

There are various reasons that patients in general choose not to participate in clinical studies. Some are not aware of available studies [8]. Others may harbor fears that the treatment will not be as effective as existing treatment or may want to expedite the treatment process beyond constraints of the research project. Trials often require multiple visits that conflict with a patient's schedule or childcare. Families may discourage participation in research [9]. Women may choose not to participate in cervical cancer screening studies because they are embarrassed, fearful of discomfort, and anxious about the severity of the results [7]. The existing literature on barriers to recruitment is largely based on anecdotal evidence, leaving a real need for recommendations based on a quantitative review of recruitment methods [10].

Because cervical cancer screening procedures are very personal and often involve some discomfort, it is necessary to study and utilize the motivations for healthy women to participate in these trials. For example, in a study on the use of *N*-(4-hydroxyphenyl) retinamide (hereafter referred to as 4-HPR) as a medication for cervical dysplasia treatment, patients reported a variety of reasons for participation, including family cancer history, desire to help others, fear of future treatment, hope that future treatment would be unnecessary, and the appeal of less invasive treatment [9]. Many of the potential participants for cervical cancer screening trials may have similar motivations as self-motivating factors such as those listed above are among the most powerful incentives for participation in clinical research in general [11]. The literature reveals that physicians also play an important role in the motivations for participation [12]. The physician influences participation through her role as the patient's source of knowledge about the clinical trial and the procedures that it entails.

The purpose of this report is to identify the most effective recruitment strategies for healthy women from the community for a trial of optical technologies for cervical cancer screening. In addition, we report the most common motivations for participation in the trials.

Methods

The cervical cancer screening trials were conducted at the University of Texas M.D. Anderson Cancer Center (MDACC), the University of Texas Health Science Center (UT HSC), and the Harris County Hospital District's Lyndon B. Johnston Hospital (LBJ) in Houston, Texas, as well as the British Columbia Cancer Agency (BCCA) in Vancouver, Canada. Recruitment began in October 2000 and is expected to end in December 2005. This paper only reports data from the women who were recruited at the Houston facilities.

The trial involves testing a new optical technology, fluorescence and reflectance spectroscopy, for detecting cervical dysplasia. Participants undergo Pap smears and colposcopically directed biopsy, as well as optical spectroscopy. The diagnostic study recruits women with a history of abnormal Pap smears, and the screening study involves females without a history of abnormal Pap smears. Some of the women in the diagnostic study were recruited from colposcopy clinics, while some were recruited from the community. All women in the screening study were recruited from the community. Women had to be non-pregnant and at least 18 years of age to be eligible.

For women recruited from the community, recruitment methods included radio and television advertisements and news stories, newspaper advertisements, newsletters, billboards, up-to-date trial information on the MDACC website, and voluntary distribution of flyers by MDACC employees at a number of different locations. Women were also recruited at fairs and festivals throughout the city. As the study began, family or friends of those who participated in the study or heard about it through the sources mentioned above were also good sources of information for potential participants. Furthermore, MDACC employees transmitted the information to friends, family, and co-workers.

Recruitment information provided prospective participants with the contact information of the research coordinator, who was responsible for an eligibility check, registration, and scheduling. Prospective participants could contact the research coordinator by telephone, e-mail, or pager. Their method of contact depended on how they were recruited. The participants' names, contact information, and how they heard about the study were recorded into a database. An organized, secure Registration and Scheduling database was created using Filemaker Pro 5.0, which was used to register participants and monitor scheduling status throughout the study. Eligibility criteria were checked, and if any uncertainties appeared, the research coordinator consulted a nurse practitioner or a physician. Those who did not meet these requirements were ineligible and were not enrolled in the trial. Participants who cancelled their scheduled appointment and did not want to reschedule, as well as those who refused to participate at the point of care, were also not enrolled. Whether they met eligibility criteria and were scheduled or were ineligible and therefore withdrawn from the study, medical data, socio-demographic information, and their participation or lack thereof in the study were recorded for all prospective participants who contacted study personnel.

Since the majority of participants were scheduled several weeks in advance, the risk of them forgetting the appointment was high. Research coordinators mailed letters that included the time and place of the screening approximately 1 to 2 weeks before a participant's appointment. Included with the letter was a map with directions, a brochure with