

Clinical Trials Recruitment and Enrollment: Attitudes, Barriers, and Motivating Factors

A Summary of Literature and Market Research Reports Held by NCI as of August 2004*
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Attitudes toward Clinical Trials

Information is limited concerning patient attitudes toward clinical trials and toward NIH/NCI clinical trials specifically. In general, positive attitudes toward clinical trials tend to increase with household income.¹

- 86% of survey respondents agree that clinical trials are important for advancing what we know about the treatment of disease.¹
- 77% of survey respondents agree that clinical trials are worth the time they take because the results can be depended on.¹
- Lower income individuals are more likely than higher income individuals to disagree with the value of clinical trials, but rather to indicate that they do not know their value.¹
- 32% of American adults surveyed indicated they would be very willing to participate in a cancer clinical trial if asked to do so and an additional 38% of adults are inclined to participate in a clinical trial if asked, but hold some questions or reservations about participating.²
- Comis et al. demonstrated that the primary problem with accrual of patients in clinical trials is not attitudes but rather the result of unavailability of an appropriate clinical trial and disqualification due to protocols.²

Lack of Information/Awareness about Clinical Trials

There is agreement in the literature that one of the major barriers to recruitment and enrollment of patients in clinical trials is patients' lack of awareness about clinical trials.³⁻⁵ 40% of adults report that they do not understand the idea of a clinical trial, meaning they do not understand the nature clinical trials or how they are performed.³ Similarly, in a study of 1,013 U.S. adults, only 34% of respondents had heard of clinical trials.³ The trend is similar with cancer patients, 85% of cancer patients sampled by NCI in a 1997 survey were not aware of clinical trials; however, 75% of these patients said they would have been willing to participate if they would have known it was possible.¹

- Awareness of clinical trials increases with household income.¹

* Based on 20 published articles, 6 NCI market research reports, 1 literature review submitted to NCI in January, 2004, and the NCI Clinical Trials Education Series.

- Physicians report that patients and their family members rarely ask about clinical trials.⁶
- Males are significantly more likely than females to have heard of a clinical trial (38% vs. 31 %) ¹
- Adults age 53 years or older are significantly more likely than those under 35 to be aware of clinical trials (39% vs. 26%) ¹
- Those residing in the West are significantly more likely than those residing in the South to be aware of clinical trials. ¹
- Only one-fourth of the population is able to describe a clinical trial. ¹
- Patients are not aware that NCI's clinical trials are free. ³

Enrollment Obstacles/What Prevents People from Participating once Recruited

There is an abundance of anecdotal information on what prevents patients from participating in a clinical trial once recruited. Most of the surveys on enrollment obstacles were not conducted with actual cancer patients who refused or were unable to participate in a clinical trial, but rather with the general public who were asked to speculate about enrollment obstacles. In general, there is consensus that perception of cost, rigid trial protocols, and fear and mistrust of researchers/medical community are major enrollment obstacles. Below is a detailed list of enrollment obstacles discussed in the literature:

- Fear of being a guinea pig. ^{4,6-10}
- Experimentation fears e.g. fear of getting a placebo and fear of the unknown. ^{8,10}
- Protocol concerns including lack of available and appropriate protocols; multiple, competing protocols; rigid inclusion or exclusion criteria; complex protocol structure; and protocols that exclude late stage cancer patients. ^{5,11,12}
 - "Three fourths of the patients referred were not enrolled because either a protocol matching their cancer site and stage was not available at the facility at which they were evaluated, or they did not meet the protocol's eligibility requirements." ¹³
 - Comis et al. concluded that the primary problem with accrual of patients in clinical trials is not attitudes but rather the result of unavailability of an appropriate clinical trial and the disqualification due to protocols. ²
- Concerns about cost including lack of insurance coverage and confusion over what is covered by Medicare. ^{3,5,7,10,12,14,15}
 - Insured patients are more likely than uninsured patients to be enrolled in a clinical trial. Fee-for-service patients are two times as likely as HMO/PPO/Medicare patients to be enrolled in a trial. ^{3,13}

- Logistical concerns including work obligations, lack of time, transportation, travel times, and lack of child care.^{6,5,8,10-12}
- Concerns about quality of life issues, e.g. loss of autonomy, side effects, and loss of functional capacity.^{3,5}
- Perceived risks outweigh perceived benefits.^{6,8}
- Information presented in the informed consent conflicts with patient's sense of hope.³
- Effort involved in the informed consent process.¹⁰
- Information about the trial is too technical.^{6,11}
- Denial of cancer.⁸
- Shock of diagnosis, overwhelmed feelings.⁸
- Belief that experience in a cancer center will be impersonal.⁸
- Preference for alternative and holistic treatments.⁸
- Concern about lack of continuity in care.⁸
- Patients may believe that a clinical trial investigator is more interested in the research than in the patient's well being.⁶
- Patients may believe that a particular treatment or intervention is ineffective.⁶
- Patients may not realize that they will receive state of the art treatment.⁶
- Patient may assume that the intervention or treatment in the clinical trial is more invasive than the standard treatment.^{6,10}

Barriers Specific to Racial/Ethnic Minorities

Racial/ethnic minorities are underrepresented in clinical research.³ One study reported that black males as well as Asian-American and Hispanic adults are accrued to clinical trials at lower rates than white cancer patients of the same age.¹⁶ There are a number of studies that address recruitment/enrollment barriers that are specific to minorities. Prevalent in the literature is a theme of mistrust of researchers among minority communities. Barriers specific to the recruitment and retention of minorities in clinical trials are listed below:

- Social and economic difficulties including lack of access to care and poor quality of care.^{3,11,14,15}
- Cultural beliefs or myths about specific diseases or illnesses.¹¹
- Fear and Mistrust.^{4,11,15 17,9,18}
- Knowledge of Tuskegee.^{3,11,18,19}
- African-Americans are somewhat less willing to participate if they believe that minorities or the poor bear most of the risks of medical research.^{18,19}
- African Americans reported in one study that time commitments, reasons for the research, whether radiation was involved, past experience with health care and research studies, family obligations, whether blood is involved, lack of childcare, and lack of information as barriers to participation in research.^{9,11}
- Belief in conspiracy theories; 99% of African American participants in one study believed that conspiracies existed or currently exist to harm African Americans.⁹
- Lack of minority physicians to recruit minority patients.³

- African-American respondents are somewhat less willing to participate (in a clinical trial) if they attribute high importance to the race of the physician when seeking routine medical care.^{18,19}
- Native Americans have a general distrust of researchers (history of disrespect, dishonesty and racism) and are more likely to utilize folk medicine.^{3,28}
- Native Americans may hold a fatalistic attitude toward cancer, and fear that if they talk or think about cancer, they might catch it.²⁸
- Native Americans may have other more pressing health issues to be concerned about.²⁸
- Asian Americans and Pacific Islanders have a cultural stigma associated with illness.³
- Asian immigrants may feel it is disrespectful to ask questions of doctors or health professionals.²⁸
- Asian cultures often make decisions by consensus, group welfare being of primary value, and individual life seen as part of the whole.²⁸
- Hispanics/Latinos may believe strongly in fatalism and resignation.²⁸
- Use of folk remedies by the Hispanic/Latino community.²⁸
- Minority women are often diagnosed at an advanced stage and have many comorbid conditions.³
- Stereotyping (by researchers and physicians) that minority patients are difficult to reach and "non compliant."^{3,11}
- Language barriers including recruitment information and consent forms not available in the language of the patient.
- Lack of valid and culturally appropriate sampling tools or questionnaires.¹⁴
- Lack of understanding and trust of informed consent procedures.¹⁷

Barriers Specific to the Medically Underserved/Economically Disadvantaged

Barriers to enrollment in clinical trials of the medically underserved and economically disadvantaged are similar to the barriers discussed for minorities including concerns about cost, transportation, and fear and distrust of researchers.^{3,11,14,15} Below are some unique barriers present in the literature for enrolling patients who are medically underserved:

- Pediatric patients are accrued to clinical trials at high levels, whereas after adolescence, only a small percentage of cancer patients are enrolled.¹⁶
- Highest observed accrual of patients for clinical trials is in suburban counties.¹⁶
- Compared to the U.S. population, patients enrolled onto clinical trials are significantly less likely to be uninsured and more likely to have Medicare health insurance.¹⁶
- Geographic areas with higher socioeconomic levels have higher levels of clinical trial accruals.¹⁶
- Illiteracy.^{11,15}
- Lack of protocols available for the disease and stage at presentation.^{11,14,15}

Barriers Specific to the Elderly

The elderly are another population that is underrepresented in clinical trials. One of the main obstacles is that physicians are less likely to refer elderly patients to clinical trials than younger patients.^{3,12} Other obstacles include:

- History of Prior Cancer.³
- Comorbid conditions.^{3,11}
- Lower levels of medical/science literacy.³
- Transportation issues.³
- Community and family serve as gatekeepers to participation.³
- Lack of trust.³
- Difficulty with compliance.³

Physicians as a Barrier

Physicians as a barrier to clinical trial enrollment are a pervasive in the literature. Most patients obtain information about clinical trials from physicians, making physicians the main gatekeeper to clinical trial information. Many physicians; however, say that they never refer patients to clinical trials for various reasons.^{3,20} Below are ways that physicians serve as a barrier to clinical trial recruitment and enrollment:

- Lack of awareness of ongoing trials, especially trials occurring at NIH.³
 - Physicians are particularly unfamiliar with prevention, diagnostic, and screening trials and often unaware of clinical trials in their geographic area.^{5,20,21}
- Feel that clinical trial design protocols are too rigid.³
- Stereotyping (by researchers and physicians) that minority patients are difficult to reach and non compliant.³
- Lack of minority physicians to recruit minority patients.³
- Ethical issues with benefit vs. risk for patients (the role of doctor conflicting with the role of researcher)³
- Difficulty with the role of the primary care physician (whether they should discuss clinical trials with patients or not). Many primary care doctors feel that it is the role of oncologists to discuss clinical trials with patients.^{3,7,20}
- Lack of time to discuss clinical trials with patients.^{5,7,12,15,21}
- Have trouble communicating with patients about clinical trial protocols and informed consent-not prepared to talk about trials-reluctant to convey complex information.³
- Concerns about uncompensated staff time to support clinical trials involvement.^{2,15}
 - "Physician bottleneck" (e.g. lack of time, limited staff resources, burden of study coordination, and data management).⁵
- Beliefs that clinical trials are inferior to current standards of care in various situations.^{20,21}
- For practitioners away from urban centers, there are concerns that participation in clinical trials would be too burdensome to patients and their families.²⁰

- Misperception that patients in the control arm of a treatment trial may receive a placebo.²⁰
- Misperception that experimental treatments are available off protocol.²⁰
- Concerns about the potential medical legal liability associated with referring patients to or enrolling patients in clinical trials.²⁰

Physician-related correlates to participation:

- Group practices are better than individual practices in recruiting patients.³
- Physicians located close to cancer centers are better at recruiting patients.^{3,16}
- Physicians who participated in NCI's community oncology program are better at recruiting patients.³
- Board certified oncologists are better at recruiting patients.³
- Protocol eligibility plays a major role in whether doctors refer patients to a clinical trial.³
- Stage of patients disease (physicians are more likely to refer patients with advanced cancer).³
- Patients with higher education levels are more likely to be referred.³
- Middle aged or very young patients are more likely to be referred than elderly patients.³

Role of Nurses in Recruitment for Clinical Trials

The role of nurses in the recruitment of patients for clinical trials was mentioned infrequently in the literature, but may be a viable way to reach patients.

- Relationship between the Clinical Research Associate (CRA) and clinical nurse can influence patient's decision to enroll in a trial.³
- CRA and/or clinical nurse can help patient overcome barriers to participation.³
- CRA and/or clinical nurse's communication style about pros and cons of clinical trials can influence enrollment.³

Motivational Factors for Participating in Clinical Trials

Reasons that patients participate in clinical trials appear to be researched less frequently than the obstacles and barriers to participating. Below are some of the most commonly listed motivations for participating in clinical trials:

- Doctor's influence/recommendation.^{1,3,22}
- Hope for a therapeutic benefit.^{3,22}
- Altruism or to advance medicine/science.^{3,22}
- Refusal to give up/no other medical option available.^{3,22}
- Trial provides meaningful cadence to day-to-day living.³
- Ability to gain access to leading specialists in a particular type of cancer.⁸
- Ability to get cutting edge care and the latest treatment discoveries.⁸

- Knowledge of Institutional Review Boards (IRB) assures patients that their well-being is as important as the scientific research.⁸
- In order to earn extra money.²²
- To obtain education about treatment/improving health.²²
- To obtain free medication.²²
- Curiosity about study/medical practice.²²

Recruitment Strategies

For the most part, recruitment strategies discussed in the literature are purely anecdotal and not based in research. However, there are many strategies that are suggested as ways to overcome barriers and obstacles to participation in clinical trials. Below are recommended recruitment strategies:

- Need for improved clinical trials literacy among patients through both doctor patient communication and better materials and messages (work needed on clinical trial terminology).³
- Use patient advocacy groups to recruit patients.³
- Improve public attitudes and knowledge about clinical trials (through media campaigns).³
- Provide clear information about clinical trial phases that isn't too technical.⁸
- Educate patients specifically about the costs involved in participating in clinical trials.⁸
- Determine key decision makers in targeted groups.¹⁴
- Advertise trials where both physicians and potential subjects will see it.¹⁴
- Offer tours of the clinic for prospective subjects.¹⁴
- Make recruitment/retention a top priority for research staff.¹⁴
- Create "user-friendly" methods for subjects/staff to comply with protocol requirements.¹⁴
- Provide feedback to referral sources about the status of a trial.¹⁴
- Speak informally to colleagues to promote protocol awareness and interest.¹⁴
- Speak at professional and community meetings about trial protocols, and request referrals.¹⁴
- Publicize eligibility requirements on brochures and flyers.¹⁴
- Provide culture and language-appropriate informational materials.¹⁴
- Contact potential subjects through fairs, community events, churches, and other resources.¹⁴
- Identify and adapt successful methods used in similar recruitment efforts for your targeted population.¹⁴
- Data from the National Lung Screening Trial indicate that inclusion of both a toll free number and a local number would be the most effective in providing trial information to potential trial participants.²³
- The Colorectal Cancer Trial Web Site Promotion Evaluation tentatively concluded that using health-related Web sites is a potentially effective vehicle for reaching both health

professionals and the general public with information about NCI-sponsored clinical trials.²⁴

Best Practices

A few recruitment strategies were identified as 'best practices':

- Involve families in clinical trials outreach and education.³
- Include minorities on clinical trials research staff.³
- Involve social workers in the accrual and retention of patients in clinical trials.³
- Establish cancer centers in institutions that directly serve hard-to-reach populations.³
- Concurrently address protocol design issues and patient recruitment.³
- Conduct marketing research to determine effective approaches to patient recruitment.³

Ways to Increase Minority Participation

- Do a better job educating minority communities about clinical trials.^{9,21}
- Provide more informational workshops on clinical trials.⁹
- Clarify the agenda behind the research.⁹
- Speak the language of the community.⁹
- Increase the number of black/minority researchers.^{3,9}
- Utilize the African American church in efforts to recruit participants.^{9,21}
- Utilize black fraternities and sororities for education and recruitment.⁹
- A majority of African Americans do not believe that certain incentives really make a difference in their decision to participate in research although some mention money and free health care as attractive incentives.⁹

Providing Clinical Trials Information to Physicians

- Most primary care physicians get information on the latest treatments from professional and medical journals, but colleagues are the main source of information on current cancer research or clinical trials.⁷
- Few physicians report using the Internet for information about the latest cancer treatment options.⁷
- Only a quarter of physicians have heard of NCI's Cancer Information Service.⁷
- Physicians want more up-to-date information about current clinical trials in order to communicate with patients about options.⁷
- Physicians are interested in having more materials and resources to help explain clinical trials to patients and families.⁷
- Improve communication to physicians and oncologists about clinical trials.³
- Develop a research network of physicians.³
- Internet delivered activities is a preferred method for Continuing Education on clinical trials.³

Use of Technology for Clinical Trials Promotion Recruitment

Little is known about the use of the Web to promote, recruit, and enroll patients in clinical trials. In a small study, 38% of respondents (cancer patients) indicated that they used the Internet to seek trial-related information, 31 % reported seeking out general disease-related information, and 12% sought out psychosocial support.²⁵

- Clinical trial patients use information on the Internet to better communicate with health care providers.²⁵
- Clinical trial patients use information from the Internet to better cope with cancer.²⁵
- Additional information/support wanted from the Internet by patients in clinical trials includes clinical trial patient networking and clinical trial result updates.²⁵
- The Colorectal Cancer Trial Web Site Promotion Evaluation tentatively concluded that using health-related Web sites is a potentially effective vehicle for reaching both health professionals and the general public with information about NCI-sponsored clinical trials.²⁴
- Internet delivered activities is a preferred method for Continuing Education on clinical trials.³

Access to the Internet

- Older Americans are much less wired than younger Americans.²⁷
- Minorities are less connected than whites.²⁷
- Those with modest amounts of income and education are less wired than those with college educations and household incomes over \$75,000.²⁷
- Rural Americans lag behind suburban and urban Americans in the online population.²⁷
- Those who are socially content--who trust others, have lots of people to draw on for support, and who believe that others are generally fair--are more likely to be wired than those who are less content.²⁷
- Those who feel they have control over their lives are more likely to be wired than those who feel they do not have much control of their lives?²⁷
- Those who read newspapers, watch TV, and use cell phones and other technologies are more likely to use the Internet than those who don't.²⁷

Conclusions/Needs for Future Research

Though a lot is known about the barriers and obstacles to recruitment of patients for clinical trials, there are still several research areas where information is lacking. First, more systematic research is needed on the most effective ways to raise awareness about clinical trials among the public, cancer patients and physicians. Lack of awareness about available clinical trials is by far the largest hurdle to recruitment. Specifically, given the context of the caMatch program, it would be beneficial to know more about Web-based strategies for raising awareness. Second, more survey data is needed on cancer patients who participate in clinical trials and on patients who refuse to participate. The majority of the existing data on motivations and barriers to participating in trials is anecdotal where physicians and the general public make speculations about why people would and would not participate. Last, more research is needed in

developing evidence-based strategies for accrual of patients in clinical trials. As shown in this document, there are many enrollment obstacles that need to be addressed through proven recruitment strategies. The bullet points below describe some additional avenues for future research:

- More research is needed on the recruitment and enrollment barriers of ethnic/minorities other than African Americans. The majority of the data on recruitment of minorities for clinical trials focuses on African Americans.
- The literature suggests that there is little known about whether using minority physicians to recruit minority patients would actually increase accrual rates.³
- The literature suggests that it is unclear whether physicians' personal monetary and practical concerns actually influence referrals to clinical trials and whether patients' sociodemographic factors correlate to physician's recruitment to clinical trials.³
- Little is known about the role or potential role of nurses in the recruitment of patients for clinical trials.
- More research is needed concerning the use of technology to recruit and enroll patients in clinical trials.
- The literature suggests that there should be more published data on how patients are actually recruited for clinical trials. "Many randomized clinical trials (RCT) published in major medical journals do not provide information about the patient recruitment process. As a result, it is difficult for readers to gauge the extent to which participants may represent a highly selected group."²⁶

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