Original Contribution

The National Cancer Institute–American Society of Clinical Oncology Cancer Trial Accrual Symposium: Summary and Recommendations

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Abstract

Introduction: Many challenges to clinical trial accrual exist, resulting in studies with inadequate enrollment and potentially delaying answers to important scientific and clinical questions.

Methods: The National Cancer Institute (NCI) and the American Society of Clinical Oncology (ASCO) cosponsored the Cancer Trial Accrual Symposium: Science and Solutions on April 29-30, 2010 to examine the state of accrual science related to patient/community, physician/provider, and site/organizational influences, and identify new interventions to facilitate clinical trial enrollment. The symposium featured breakout sessions, plenary sessions, and a poster session including 100 abstracts. Among the 358 attendees were clinical investigators, researchers of accrual strategies, research administrators, nurses, research coordinators, patient advocates, and educators. A bibliography of the accrual literature in these three major areas was provided to participants in advance of the meeting. After the symposium, the literature in these areas was revisited to determine if the symposium recommendations remained relevant within the context of the current literature.

Results: Few rigorously conducted studies have tested interventions to address challenges to clinical trials accrual. Attendees developed recommendations for improving accrual and identified priority areas for future accrual research at the patient/community, physician/provider, and site/organizational levels. Current literature continues to support the symposium recommendations.

Conclusions: A combination of approaches addressing both the multifactorial nature of accrual challenges and the characteristics of the target population may be needed to improve accrual to cancer clinical trials. Recommendations for best practices and for future research developed from the symposium are provided.

Introduction

Cancer clinical trials provide the evidence base for new advances in oncology. Poor enrollment onto trials threatens to slow progress in cancer care at a time when advances in science are enabling new opportunities for prevention and treatment.[1] Enrollment among racial/ethnic minority, elderly, adolescent, and young adult populations in particular may not be adequate to address aspects of care unique to these populations.[2-4] Various challenges to enrollment have been documented at the patient/community, physician/provider, and site/organizational levels.

Patient/community awareness and knowledge about clinical trials are variable.[5-8] Some of the most commonly cited patient-centered concerns that deter participation include understanding of and attitude toward randomization or assignment to placebo or nontreatment, potential adverse effects and impact on quality of life, unease with research, and protocol complexity.[6,7,9-17] Financial burden and logistics, such as driving dis-

tance, also compromise participation, especially among older, rural, and minority patients.[16,18-21] Trust in the physician, particularly when a physician recommends a trial, is highly associated with patient recruitment.[8,17,22-26] Unfortunately, some studies show that many oncologists do not suggest clinical trials to potentially eligible patients, even though patients have been shown to be generally receptive to trial participation.[8,16,26]

Physician/provider–related deterrents include concerns about tolerability, patient age, comorbidities, and poor prognosis; provider attitudes toward research and concerns about demands on staff; and unconscious biases and/or lack of cultural competence.[7,10,12,15,27-35] Many oncologists view clinical trials only as an option of last resort.[7] Myriad logistical and regulatory challenges to engaging in clinical research can serve to dissuade physicians from participation.[1,36,37] Finally, clinicians, including nurses, may not feel comfortable discussing trials with their patients.[26,38-48]

Site/organizational challenges include lack of institutional support; insufficient staffing, especially research nurses and support staff for more complex studies[7,49,50]; unavailability of suitable protocols at the site[30,51-55]; long protocol review and activation times[56,57]; ineffective operational procedures; and no formal mechanism for eligibility screening.[58]

Recognizing these continued challenges, the National Cancer Institute (NCI) and the American Society of Clinical Oncology (ASCO) cosponsored the "Cancer Trial Accrual Symposium: Science and Solutions" on April 29 to 30, 2010. The goals were to

- Present evidence-based trial accrual strategies from among a variety of patient populations, settings, cancers, and trials
- Promote innovative strategies to address common challenges in clinical trial accrual, including recruiting and retaining minority and under-served populations
- Identify recommendations for future research.

This article describes the recommendations that resulted from the symposium.

Methods

The symposium was designed to complement initiatives being carried out at the national level, such as those recommended in the Institute of Medicine report on reinvigorating the NCI trials system, and reports from the NCI's Operational Efficiency Working Group and Clinical Trials Working Group.[1,59-61] The Symposium explicitly did not focus on approaches at the sponsor and regulatory levels (eg, reimbursement or insurance policy, trial design). Rather, it sought to identify approaches that could be implemented "on the ground," at the patient/community, provider, and site levels.

The symposium was planned by a steering committee formed by the NCI and ASCO with accrual expertise from varying perspectives, including those of patient advocates, an NCI Cooperative Group chair, NCI-Designated Cancer Center clinical research directors, NCI Community Clinical Oncology Program (CCOP) and Minority-Based CCOPs (MB-CCOPs) principal investigators, NCI Clinical Trials Program directors and nurse consultants, ASCO's Cancer Research Committee chair, epidemiologists, bioethicists, research psychologists, and experts in management research. Among the 358 symposium attendees were investigators conducting research on accrual strategies, clinical investigators, research administrators, nurses, research coordinators/associates, patient advocates, MB-CCOP representatives, and educators.

Before the meeting, a bibliography covering 2004-early 2010 was provided to participants, taking as its starting point the cutoff date of major reviews published at the time.[6,31,62] After the symposium, the literature was revisited to determine whether the symposium recommendations remained relevant within the context of the current literature.

The symposium was organized into initial background and goal-establishing presentations; breakout, poster, and plenary sessions; and, finally, summary presentations. Three major breakout sessions, facilitated by invited expert faculty, addressed the following areas:

1. Patient- and community-centered solutions (patient participation, decision making, and informed consent; minority and under-represented populations; community outreach, education, and participation)
2. Physician/provider-centered solutions (physician/provider communication; recruitment planning and evaluation)
3. Site-centered–organizational solutions (effective leadership and organizational culture to promote accrual; trial selection, infrastructure, and operations)

One hundred abstracts were accepted for the poster session after a call for abstracts on successful accrual studies and practices. The four highest-rated abstracts were selected for plenary presentations.[63-66]

To ensure consensus based on a range of stakeholder input, each breakout session was organized to be inclusive of academia, community investigators and leaders, and patient advocates. Faculty helped to integrate meeting abstracts with the published literature and attendee input to develop the recommendations. On the final day of the meeting, summary presentations gathered further input on the recommendations from all participants.

Results

A number of recommendations for implementation and future research were developed. Participants generally agreed that different strategies must be tailored to the different learning styles of potential study participants, as well as to the unique needs of different types of trials, their research questions, and their study design.

Attendees felt there was a lack of published, methodologically rigorous research on which to base strategies for improving accrual. Indeed, only a small proportion of studies discussed at the symposium have been published as full-length manuscripts.[44,45,55,65,67-74] Three of these describe approaches implementable at the patient/community, provider, or individual site level that led to increased accrual: namely, site recruitment planning in the National Lung Screening Trial (NLST) trial;

direct phone contact for a genetics registry; and a multipronged, culturally specific approach at a major cancer center.[17,65,70] It is not surprising that the article on NLST recruitment found that no one single strategy was successful across all sites.[70]

Many published studies have sought to evaluate interventions for improving accrual or to identify factors associated with higher accrual to cancer trials. Reviews have noted, however, either that methodological limitations of these studies prevent evidence-based conclusions from being drawn from them or that there is no clear indication that many of the interventions did, in fact, lead to higher accrual.[31,75-81]

Seventy of the 100 symposium abstracts are available by searching "NCI ASCO Cancer Trial Accrual Symposium" at AccrualNet (https://accrualnet.cancer.gov/).

Patient/Community Level

Symposium recommendations. Table 1 lists recommendations for implementation and for research at the patient/community level that resulted from the symposium. Recommendations urged the involvement of patient advocates, community leaders, representatives of target minority groups, peer mentors (ie, others who have participated in a clinical trial), and patient navigators to enhance recruitment and retention. Also discussed were approaches used in community-based participatory research, which welcomes community stakeholder participation in trial development. There was support for the use of screening logs, advocates, and focus groups to capture patient perspectives on trial participation, including why eligible patients declined.

Participants urged further research on decision making and patient-provider communication. Calls for improvements to lengthy and complex consent documents were made, to facilitate presentation of trials and help patients better understand trials.

Literature review. Raising general awareness about clinical trials alone does not appear to translate into improved accrual.[11,37,69,82-84] However, a recent randomized intervention using Web-based clinical trials information as text, or tailored video content, both improved attitudes, knowledge, and preparation of patients considering a trial.[85] Social marketing—particularly direct mail, news radio advertisements, fliers, newspapers, and clinical trials Web sites—may be more effective in prevention trials than other recruitment approaches,[79,86-91] but not consistently,[92] and may need to be complemented by personal contact.[65,93,94] Community-based approaches have shown particular promise in nontherapeutic trials.[95-99]

Engaging patients in learning about the health problem itself and allowing more time between diagnosis and the patient's enrollment decision may promote enrollment.[11,32,53,100] One-on-one extended discussion with a qualified member of the research team,[101,102] decision aids,[103] and simpler consent forms could serve to further increase patient understanding when a trial is being offered.[104-107]

Some successes have been reported from use of trial-matching services, including the Clinical Trials Matching Service, and even Craigslist.[108,109] Studies using registries for identifying potential research participants for cancer trials have been few.[86,110,111]

Physician/Provider Level

Symposium recommendations. Table 2 lists recommendations for implementation and for research at the physician/provider level that resulted from the symposium. A consistent theme heard throughout the symposium was that institutional commitment and strong leadership are key components of successful accrual. Especially important are physicians engaged in clinical trials with dedicated research teams, backed by a multidisciplinary approach.

Participants called for research that sought to determine which communication practices are most effective in promoting accrual and what sort of physician/provider training works best to instill those practices. Some urged integrating competency-based education into all health professions students' curricula.[112] Many emphasized the need to provide clear information on routine care costs and potential financial liability the patient might incur by participating in a trial, to enhance informed consent discussions.

Abstracts presented demonstrated how physician and nurse education strategies could enhance provider attitudes and beliefs about clinical trials.[113,114] One plenary presentation proposed qualification of clinical investigators based in part on actual accrual performance.[63] Symposium participants also stressed the importance of incentivizing provider participation, by offering protected time, administrative support, training, and participation in professional meetings.

Literature review. Investigator commitment to research appears to be paramount. Physicians who spend more time with each new patient, are affiliated with a CCOP/MB-CCOP or NCI-Designated Cancer Center, have a history of commitment to recruiting patients for clinical trials, were involved in the planning and implementation of a trial, and/or see a higher number of patients have higher enrollment rates.[57,92,115,116] Multidisciplinary discussion of a trial, especially during tumor boards, has also been linked to higher accrual, as has past physician attendance at educational sessions on cancer treatment trials.[32,115-120] Evidence of the impact of educating referring physicians about clinical trials, though, is still mixed.[25,79,89,92,121-123]

Enhanced physician communication with patients may also increase enrollment. Patients are more likely to enroll in a trial if the physician discusses the possibility of trial participation, explains adverse effects and possible benefits, behaves in a caring way, and discusses patient concerns and resources for addressing those concerns.[8,41] Video recording has been used to study the manner in which physicians offer trials to patients.[124] Although changing provider communication styles is not always easy,[39] results of some training programs have been promising.[12,125,126]

Careful recruitment planning during protocol development that includes members of participant communities is associated with positive accrual outcomes. The Selenium

Table 1. Patient- and Community-Centered Recommendations

Best practices
1. Consider the patient point of view, including potential barriers, when reviewing and implementing trials. Patient advocates should be part of this effort.
2. Identify and address reasons why eligible patients decline trial participation, for example, via screening logs and focus groups.
3. Simplify informed consent documents and enhance personal communication during the informed consent process, including clarifying possible financial liability the patient may incur by participating in the trial.
4. Educate patients and the community, including community providers, about clinical trials, using culturally appropriate material.
5. Involve advocates and/or advocacy organizations in education about trials and in trial promotion.
6. Engage racial/ethnic minority and other underserved communities to help develop strategies to increase access to clinical trials.
7. Involve community leaders in the design and implementation of trials that are important to them, to ensure buy-in and cultural sensitivity.
8. Use principles of community-based participatory research that involve engaging the community in the research development process when appropriate.
9. Explore the use of social media, patient registries, and electronic databases to enhance recruitment to prevention, quality-of-life, survivorship, and rare-cancer studies.
10. Provide access to peer mentors (other patients who have participated in a clinical trial) and patient navigators for those patients identified as in need of additional support.
11. Include multilingual staff and medical interpreters as members of the research team.
Future research
Patient decision making
• Develop and test interventions tailored to the needs of different patients' demographics and communication preferences. Such interventions may include communication strategies and use of decision aids. Future research must address the multiple factors that influence patient decision making.
• Evaluate the impact of patient navigators, advocates, and recruitment specialists on accrual.
Racial/ethnic minority and underserved populations
• Develop and test culturally sensitive educational tools/interventions. Strategies should seek to overcome patient-based factors among various minority and underserved communities, including attitudinal and logistical factors.
• Identify and evaluate key site infrastructure components (eg, focused patient navigators and multilingual staff) of successful minority clinical trials programs and evaluate their implementation at other sites. Build this evaluation into an established trial design. Study and learn from successful initiatives in therapeutic and prevention trials among the Cooperative Groups, Minority-Based CCOPs, and other research programs.
Community involvement
• Conduct studies of educational interventions that evaluate not only improved patient understanding, but also changes in enrollment rates.
• Evaluate the ability of Community Advisory Boards and/or community-based participatory research to improve community perceptions of and participation in clinical trials.
• Identify factors that facilitate physician referral and community provider participation in clinical research.

Abbreviation: CCOP, Community Clinical Oncology Program.

and Vitamin E Cancer Prevention Trial (SELECT), which completed its recruitment two years ahead of schedule, had an active accrual planning committee that included focus group recommendations among their strategies. Likewise, the NLST saw increases in its recruitment of members of racial/ethnic minorities among those sites that implemented targeted recruitment strategies compared with those sites that did not.[70,127] Recruitment planning strategies have been described in the literature but not studied comparatively in cancer trials.[128-135]

Site/Organization Level

Symposium recommendations. Table 3 lists recommendations for implementation and for research at the site level that resulted from the symposium. It was strongly felt that site/organizational culture and leadership play important roles in predicting accrual success. Moreover, participants believed clinical leadership could learn from principles of business management, such as commitment to a unifying vision and common incentives, as well as from sociology, anthropology, and operational engineering.

Symposium attendees discussed the importance of sites benchmarking and monitoring their accrual performance against similar sites and realistically planning for staffing and workload, numbers and complexity of trials, and the impact of technological innovations (eg, protocol management software). Trial complexity metrics were suggested to help guide these assessments.[71,136]

Use of screening logs was recommended to identify eligible patient populations and track reasons for screen failures, in order to address them.[63,137] It was thought that use of formal process improvement techniques, such as "lean" and "six-sigma" practices, could help streamline local processes for opening and conducting clinical trials.[138]

Finally, participants recommended studying both successfully accruing and poorly accruing programs to glean lessons from their organizational approaches. In one of the plenary presentations, Ohio State University Comprehensive Cancer Center presented the results of its "2010 by 2010" campaign to increase clinical trial accrual.[64] This campaign used a multipronged approach that included educating patients and referring physicians through various media; specific staff training led by cancer center leadership; and charging disease-specific committees with monitoring accrual, activation times, and suitability of the trials portfolio for their own disease area. They reported a 40% increase in accrual during the intervention period (2007-2009).

Table 2. Physician/Provider-Centered Recommendations

Best practices

1. Develop evidence-based training initiatives to improve provider communication when discussing a trial with a patient. Physician leaders should educate colleagues about such initiatives and serve as mentors in training new researchers and staff.
2. Provide incentives for clinicians to participate in research. Incentives may include protected time, administrative support, training, and participation in professional meetings.
3. Disseminate availability of local trials to primary care providers and other referring providers through the mechanisms most widely used in that community, using culturally appropriate material.
4. Recruit investigators from minority/underserved communities.
5. Provide ongoing feedback to referring physicians while their patients are on a trial.
6. Adopt elements of recruitment planning and work with research teams to ensure commitment to such plans. Elements could include screening, enrollment, and retention rates; identification of sources for accrual; contingency strategies for slow accrual; and evaluation of those strategies.
7. Use information technology, such as registries and electronic health records, to identify potentially eligible patients more efficiently and reduce chart-review time.
8. Publish on strategies that led to successful accrual to trials. Methodologically rigorous studies of accrual interventions are needed in the literature.

Future research

Physician/provider communication

- Study physician and research team communication with prospective trial participants and identify the most successful and efficient methods for improving patient understanding of trials, accrual, and satisfaction with care. This could involve comparing the ways in which high- versus low-accruing physicians and/or research teams communicate with their patients.
- Test the effectiveness of training physicians and research teams in these communication methods and evaluate for improvements in patient understanding of trials, accrual, and satisfaction with care.
- Identify the optimal timing to offer and discuss clinical trials with patients, including timing relative to initial diagnosis and presentation of treatment options.

Recruitment planning and evaluation by investigators

- Determine which recruitment strategies are most helpful for specific types of studies.
- Embed accrual studies in appropriate Cooperative Group trials to generate evidence-based strategies for recruitment (ie, prospective testing of recruitment interventions).
- Identify meaningful metrics for evaluating recruitment strategies and the impact of correction plans, in real time, on improving accrual.
- Assess the impact on accrual of using documented, comprehensive recruitment plans.
- Test the use of screening logs as a recruitment evaluation tool.
- Evaluate the utility of patient registries, databases, and electronic tools for increasing accrual, such as those offered through NIH's Clinical and Translation Science Awards ResearchMatch[176,177] and NCI's AccrualNet,[172,173] which may have potential benefit for busy sites.

Abbreviations: NCI, National Cancer Institute; NIH, National Institutes of Health.

Literature review. Although institutional best practices to promote accrual to clinical trials have been offered, there is little research on how organizational and leadership aspects of cancer clinical trials affect accrual.[1,64,139-150] In the noncancer literature, there is some evidence that organizational characteristics such as administrative and clinical staff support and infrastructure may actually influence accrual more than any specific recruitment intervention.[151]

It is apparent no single organizational characteristic determines high accrual to cancer trials. For example, having many cancer treatment trials open combined with having either many new patients with cancer or many affiliated sites has been associated with higher accrual.[152] Use of a central institutional review board (IRB) may expedite site activation, and therefore accrual.[56,153] In addition, CCOP presence in a county has been found to be associated with higher accrual and/or trial participation.[99,111,115]

Addition of staff has been associated with improved accrual or retention, including the addition of patient navigators,[154] and dedicated staff for specific trials or functions, such as eligibility screening.[102,155-158] Although patient navigators are being engaged to assist minority enrollment to trials, their use remains understudied.[55,150,159-162] Workload management tools have been developed to assist sites in allocating adequate staffing to clinical trials.[50,71,163-165] In addition, software for automating eligibility screening has been shown to substantially reduce staff hours spent on screening.[74]

Lessons could also be drawn from success stories. After restructuring its cancer program in 2001, the Helen F. Graham Cancer Center saw its NCI clinical trials accrual rate increase from 9.9% to 20% between 2001 and 2006.[166] Restructuring involved establishing multidisciplinary disease site centers, placing research nurses in private-practice offices, and a continuous marketing campaign. Trial activity grew further after the implementation of clinical trialist performance standards that held investigators to accrual standards.

An intensive recruitment intervention used in the Prostate Testing for Cancer and Treatment (ProtecT) trial led to an increase in immediate acceptances of randomization from 65% to 81% between 2001 and 2005. The intervention involved regular staff training, reviews of under-enrolling sites, reviews of audiotaped discussions of physicians and staff with patients, and individual feedback to improve communication practices.[167,168]

Discussion

The Cancer Trial Accrual Symposium sought to gather the expertise of the cancer clinical trials community to describe current best practices for promoting accrual at the patient/community, physician/provider, and site levels, to complement ongoing efforts at the national level to improve the US clinical trials system, particularly the NCI-funded Cooperative Group Program.[1,59-61]

Table 3. Site-Centered Recommendations

Best practices
1. Promote accrual through leadership best practices and organizational development. This may include establishing a "culture of commitment" to clinical trials from the highest levels at a site as part of standard of care, including multidisciplinary teams that prioritize clinical trials.
2. Implement site and clinical trialist performance standards that qualify clinical investigators based in part on their accrual performance.
3. Use available site data, including screening logs, to verify that patient populations are available for trials the site is considering, and to identify patient populations at the local level who lack available trials.
4. Promote leadership/ownership of investigator-initiated trials.
5. Use formal quality improvement techniques to increase the efficiency of opening and conducting trials.
6. Use a clinical trials management system as a tool to track the various aspects of managing protocols and empower a Steering Committee or core team to utilize it to evaluate site progress.
7. Close trials that fail to accrue at a reasonable pace, with allowances for variable rates for less common tumor types or more rare disease settings.
8. Use the NCI's Central IRB (CIRB) for NCI Cooperative Group trials to shorten IRB turnaround times and reduce workload of local IRBs, particularly with the new CIRB Independent Model.
Future research
Site leadership, organization, and operations
• Study both successfully accruing and poorly accruing sites for lessons learned regarding their organizational and leadership strategies, as well as their infrastructure, staffing, and trials portfolio. Test new organizational models and evaluate their impact on accrual. Models are especially needed for private-practice trials unsupported by an academic institution.
• Identify, implement, and then evaluate leadership models effective in other fields, such as commercial enterprise, that may also be applicable to improving accrual to clinical trials. Consider engaging anthropologists, sociologists, and operations engineers in developing these leadership models.

Abbreviation: IRB, institutional review board; NCI, National Cancer Institute.

Symposium participants recognized the need for a multidisciplinary approach that is consistently backed by the leadership of respective institutions. Given the multifactorial nature of accrual challenges and target populations, a combination of approaches is needed to improve accrual, and input on approaches should be gathered from a variety of stakeholders.

The current literature continues to support the recommendations resulting from the symposium. Corroborating concerns expressed by symposium participants, our literature review found that rigorous studies of accrual interventions have been lacking in the published literature.[31,75-80] This gap hampers conclusions about what approaches, in what contexts, are effective for improving accrual to cancer trials.

We are at a key juncture, however, to consider the symposium recommendations. Trial eligibility is becoming increasingly molecularly defined, necessitating more intensive screening and selection of patients.[169] Moreover, at the time of this report, a major program to reinvigorate the clinical trials system at the national level is being implemented on the basis of Institute of Medicine recommendations.[1] To be launched in early 2014, the NCI National Clinical Trials Network will transform the NCI Cooperative Group Program into a new, integrated network designed to operate in a more collaborative, coordinated way.[170]

The collaboration envisioned in the National Clinical Trials Network could include sharing of successful accrual approaches and the study of these approaches as embedded studies in appropriate trials. Although somewhat outside the scope of the symposium, embedding accrual intervention studies in large trials was a recommendation heard repeatedly throughout the symposium (eg, testing an educational intervention to improve patient understanding about randomization in a phase III clinical trial). It was felt that this approach could provide the type of prospective, scientifically rigorous evaluation needed to generate evidence-based strategies. Existing trials could also report on strategies they used to ensure successful completion.

Symposium participants also called for improved clarity regarding what is financially covered in trials, such as tests and procedures that may be routine versus research. Standardizing this information, such as through use of protocol-specific billing templates that provide information on possible financial liability, would facilitate informed consent and local site review processes. SWOG (formerly the Southwest Oncology Group) is piloting an effort to address this issue by providing coverage analyses for sites (Kati Stoermer, personal communication, May 9, 2013).

Whereas rapid completion of clinical trials is a societal imperative, the patient's decision about whether to participate is an individual one. Hence, patient-directed interventions should focus on optimizing decision making rather than enrollment per se. We believe, however, that improved decision making will result in greater clinical trial participation by patients. Recently, NCI revised its informed consent form template to simplify consent forms, which may increase their utility during the consent process.[171]

Useful resources for sites wishing to improve their accrual include NCI's AccrualNet Web site, and *Journal of Oncology Practice*'s Clinical Research Practices section.[172-174] ASCO's Statement on Minimum Standards and Exemplary Attributes of Clinical Trial Sites provides recommendations for research sites interested in developing high-quality research programs and creating a "research-centered culture."[175]

Clinical trials should be considered as an option in the care for all patients with cancer, regardless of their socioeconomic status or where they choose to receive their care. If all sites participating in cancer clinical trials identify ways in which to improve their own accrual, we will be able to advance cancer research more rapidly and ultimately improve the lives of people at risk for or diagnosed with cancer.

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