

Interventions to improve access to clinical trials in urologic oncology

Adam Hass¹, Jonathan C.A. Guzman^{1,2}, Michael A. Feuerstein^{1,2}

¹Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY, United States; ²Department of Urology, Lenox Hill Hospital, New York, NY, United States

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ABSTRACT

INTRODUCTION: Most cancer patients are never enrolled in clinical trials, resulting in missed potential therapeutic benefits to patients and barriers to drug development and approval. With a focus on urologic oncology clinical trials, we reviewed the current literature on barriers to accrual and present effective interventions to overcome these barriers.

METHODS: PubMed was searched for articles regarding physician referral and patient accrual to clinical trials in urologic oncology from January 2000 through June 2021. Studies were included if they were in English, related to clinical trial utilization or patient accrual in urologic oncology, peer-reviewed, primary research, survey, or systematic review, and pertained to clinical trials in the U.S. Major overlapping themes related to barriers to accrual and effective interventions were identified.

RESULTS: Thirty-six studies met our inclusion criteria. Barriers fall into three categories: 1) provider; 2) patient; or 3) structural. Provider barriers include issues such as poor funding, logistical challenges, and time constraints. Patient barriers include cost, distrust of medical institutions, and lack of knowledge regarding ongoing studies. Structural barriers include lack of time and resources in community settings and difficulty with physician referrals. Effective strategies identified include increasing provider referrals through continuing education and referral pathways, increasing patient education through patient-centered marketing material, and decreasing structural barriers through patient navigation programs and community partnerships.

CONCLUSIONS: We identified barriers and potential multipronged strategies targeted at patients, providers, and practices to increase clinical trial enrollment. We hope these strategies will benefit patients and providers and facilitate research development.

INTRODUCTION

Prospective clinical trials can provide patients with novel therapeutic options and are the most effective tools for research development, measuring the effectiveness of interventions and drugs, and setting the standards of care. The National Comprehensive Cancer Network and the American Urological Association base their strongest guideline recommendations on prospective clinical trials. Despite the recognized importance of incorporating clinical trials into patient care, and although a large majority of cancer patients are willing to participate in clinical trials, it is estimated that only 8% of adult cancer patients in the U.S. participate in clinical trials.¹⁻³ Between the years 2000 and 2011, 18% of cancer clinical trials in the National Cancer Institute's Cooperative Group Program, now the National Clinical Trials Network, closed with less than 50% of desired patient enrollment within three years of the start of the trial.⁴

Notably, urologic oncology has the highest rate of trial failure within urology, most often due to poor patient accrual.^{5,6} In urology, clinical trials tend to accrue patients slowly despite positive attitudes from practicing urologists towards clinical trials and their potential benefits to patients.⁷ As a surgical subspecialty, urologic oncology trials face many of the challenges of surgical trials in general, including an inability to standardize surgeon skill, anesthesia, surgical approach, instrument choices, postoperative management, and ethics surrounding blinding/sham controls.^{6,8}

KEY MESSAGES

- Urologic oncology has the highest rate of trial failure within urology, most often due to poor patient accrual.
- Barriers to accrual in urologic oncology clinical trials include recruitment, cost, structural considerations, and patient and provider obstacles.
- Dedicated referral pathways/hotlines, patient navigation programs, social marketing, and community partnerships have all been shown to increase recruitment and accrual.

All of this is evidenced by a troubling trend: the decision to enter a clinical trial is often made after the medical treatment has already been decided, thus eliminating the possibility of referral to clinical trials.⁹ Therefore, these barriers to clinical trial accrual can result in real changes to patient care plans, which have the potential to adversely affect clinical outcomes and further highlights the need for proactive interventions to increase research trial referrals and recruitment.

The objective of this study was to provide a narrative review of the relevant literature on urologic oncology clinical trial use and present a holistic view on the barriers faced on both the patient and provider level. We examined selected interventional strategies shown to increase clinical trial accrual and success.

METHODS

We searched the PubMed database for studies on barriers to accrual in urologic oncology trials specifically from January 2000 to June 2021. Combined search terms included: “urology + oncology,” “urologic oncology,” “clinical trial utilization,” “patient accrual,” “barriers,” “interventions,” and “increasing accrual.” This yielded 433 papers. The authors then reviewed article titles, abstracts, and full texts. Studies were included if they satisfied the following criteria: 1) written in English; 2) related to clinical trial utilization or clinical trial patient accrual in urologic oncology; 3) peer-reviewed; 4) primary research, survey, or systematic review; 5) pertaining to clinical trials in the U.S. After review, 10 studies were suitable for the analysis and included into the present study per database search.

We then further examined and explored articles pertaining to barriers and interventions for patient accrual that were referenced by the 10 initial selected studies. For these articles, our inclusion criteria were: 1) written in English; 2) related to clinical trial utilization or clinical trial patient accrual in oncology (including non-urologic oncology); 3) peer-reviewed; 4) primary research, survey, or systematic review; 5) pertaining to clinical trials in the U.S. From these criteria, 26 additional articles relating to patient accrual in oncology, even if not specific to urologic oncology, were include in the review if cited by articles in the primary search. These are summarized in Figure 1.

RESULTS

Several factors serve as barriers to accrual in urologic oncology clinical trials, including recruitment, cost, structural considerations, and patient and provider factors, summarized briefly in Table 1.

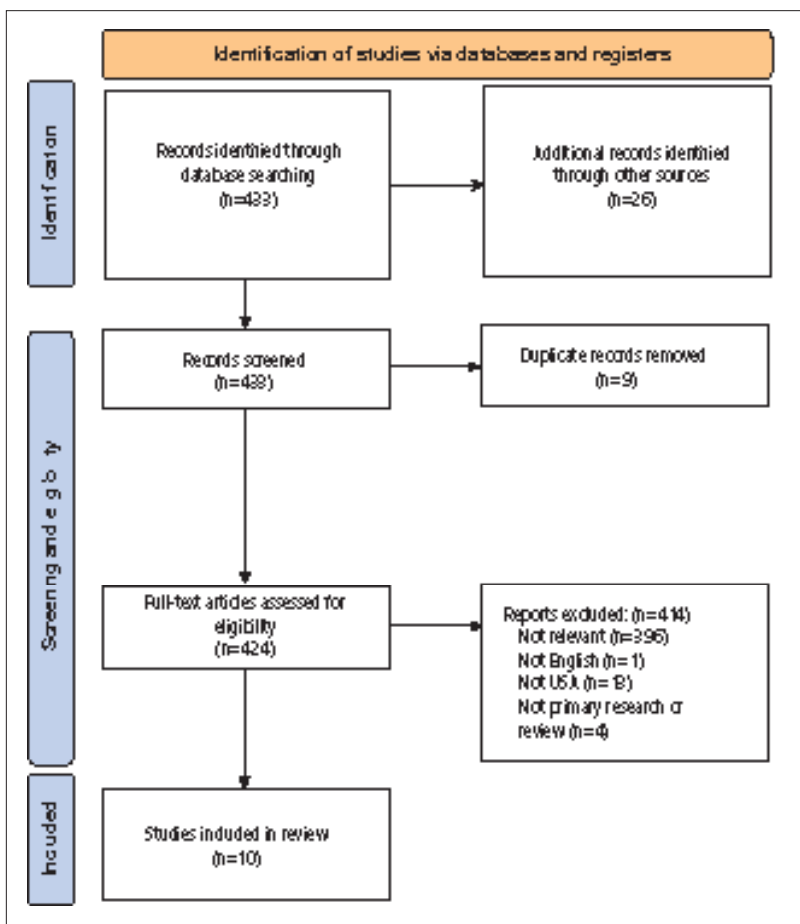


Figure 1. RISMA diagram summarizing the search methodology and inclusion criteria for reviewed studies.

Provider barriers

Community urologists are less likely to report access to clinical trials than their academic counterparts and few report offering clinical trials to patients.^{7,10} The National Cancer Institute (NCI)'s Community Oncology Research Program, which has successfully increased community physician referral to clinical trials, does not include urologists.¹¹ Bandari et al demonstrated that poor accrual was the predominant reason (41%) for clinical trial failure in urology. Although not necessarily within the scope of provider control, though still affecting providers nonetheless, Bandari et al found that other reasons for trial failure included inadequate budget (9%), sponsor cancellation (7%), poor interim results (7%), and toxicity (3%).⁶

Urologic cancer accounts for 20% of the incidence of all cancer in the U.S.,¹² yet 17% of urologic oncology trials fail, most frequently due to poor accrual, consistent with oncology trial studies in general, which estimate a 20% failure rate.^{13,14} Stensland et al noted that of the 225 urologic oncology trials that failed, 122 (54%) failed due to poor accrual. Other reasons for trial failure in this study included sponsor cancellation (8%), principal investigator leaving the institution (2%), logistics (1%), and inadequate budget (5%).¹³ Greater resources, i.e., funding, alone cannot solve the accrual problem. Parker et al noted that trials with greater resources, including multinational resources, multicenter trial locations, and larger accrual goals, fail less frequently than other trials; however, simply devoting more resources to existing trials may not be an efficient means to improve trial conduct, increase accrual and referral, or improve patient outcomes. The authors found that increasing a study's budget alone did not lead to statistically significant increases in trial recruitment.¹⁵

Ellis et al noted that urologists tend to have established referral networks that do not always include institutions involved in clinical trials or ways to learn about trial availability, accessibility, and inclusion/exclusion criteria.¹⁰ As a result, patient eligibility poses a problem for urological clinical trials. Urologists often lack knowledge about the eligibility criteria for a study and do not understand the accountability for eligibility screenings. This leads to many potentially eligible patients being lost to followup because it is unclear whether eligibility screenings will be performed by the referring physician or the primary research institution conducting the study.¹⁰

Patient barriers

Financial toxicity to patients could be a significant barrier to accrual. Kilgore et al highlight the increasing

Table 1. Summary of identified barriers to trial accrual in urologic oncology clinical trials, grouped as provider-related, patient-related, and structural

	Barrier	Study	Impact
Provider-related	Poor accrual	Bandari et al ⁶	41% of trial failures
		Stensland et al ¹³	54% of trial failures
	Inadequate budget	Stensland et al ¹³	5% of trial failures
		Bandari et al ⁶	9% of trial failures
	Sponsor cancellation	Bandari et al ⁶	7% of trial failures
		Stensland et al ¹³	8% of trial failures
	Poor interim results	Bandari et al ⁶	7% of trial failures
	Toxicity	Bandari et al ⁶	3% of trial failures
	PI left institution	Stensland et al ¹³	2% of trial failures
	Logistics	Stensland et al ¹³	1% of trial failures
Patient-related	Lack of physician awareness	Ellis et al ²¹	Patients are not informed of available clinical trials
	Patient eligibility/screening process	Ellis et al ²¹	Patients lost to followup due to lack of clear workflow
	Out-of-pocket costs	Kilgore et al ¹⁶	Patients pay average of \$131/6 month period compared to non-trial participants
	Lack of time off/travel time	Kilgore et al ¹⁶	Increased cost to patient
	Lack of health insurance	Kilgore et al ¹⁶	Increased cost to patient
	Low-income	Unger et al ¹⁷	Lowest-income patients 23% less likely to participate
Structural	Inclusion/exclusion criteria & comorbidities	Chalela et al ²⁰	3-12% of interested/referred patients excluded from trials
	Patient attitudes about clinical trials	Ford et al ¹⁸	E.g. mistrust of research, fear, perceived harms of interventions, religious beliefs, etc.
	Practice credentialing	Ellis et al ²¹	Bureaucratic hurdles before referral to trial can begin
	Administrative workload	Ellis et al ^{10,21}	Lack of personnel increases burden on providers
	Lack of informational Resources	Ellis et al ¹⁰	E.g. brochures, informational videos, internet sources, etc. not readily available
	Delayed introduction to trials	Logan et al ⁹	Patients introduced to clinical trials after treatment decisions made

out-of-pocket costs for patients.¹⁶ With many oncologic clinical trials taking place at specific NCI centers, distance from the trial center may increase the travel

Table 2. Summary of studied interventions to previously identified barriers, grouped as provider-related, patient-related, and structural

	Intervention	Study	Impact
Provider-related	Dedicated referral pathway	Ellis et al ²¹	Regular communication and point of care flowsheets increase patient referrals from community practices while reducing burden on physicians
	Referral hotline	Ellis et al ²¹	Urologists and patients can call to start trial enrollment process
	Continuing education	Ellis et al ¹⁰	'Meet the researchers' workshops and quarterly newsletters promotes working relationships
Patient-related	Culturally adapted recruitment cards	Wenzel et al ²⁹	Increased recruitment rates of under-represented populations
	Social marketing	Heiney et al ³⁰	Plain language, testimonials from community leaders, and patient quotations increase recruitment
	Patient-centered communication strategy	Green et al ³²	E.g., targeted and empathetic communication strategies led to a 373% increase/11 month period in patient accrual
Structural-related	Branded marketing	Ellis et al ¹⁰	Helps referring physicians initiate conversations about trials and improves patient attitudes
	Bilingual patient navigation programs	McClung et al ²²	Use of patient navigators in cancer trials improved patient attitudes
	Patient navigation programs	Green et al ³²	Patients enrolled in navigation programs were 4.88x more likely to complete trial
	New methods of consent	Borno et al ³³	Engaging patients in community settings reduces travel burden, increases accrual
	Telehealth	Baca-Motes et al, ³⁵ Carceres et al, ³⁶ Bobb et al ³⁷	Adapts consent process to shutdowns, lockdowns, and quarantines
	Community partnerships	Petereit et al ³⁸	Establishing trusting partnership with community, (e.g., navigators, transportation) led to 96% success rate within 10 months

costs for the patient, which may already be substantial. Additionally, a lack of sick time or sick leave from the patient's employer to travel to and attend clinic and research visits may increase costs and present an insurmountable barrier to the patients joining research trials. Similarly, not having health insurance increases costs to the patient.¹⁶ In fact, low-income patients have been shown to be less likely to enroll in oncology clinical tri-

als. Unger et al note that income remains a statistically significant predictor of clinical trial participation; compared to patients making \$100 000 annually, patients making \$20 000 per year were 23% less likely to participate in a cancer clinical trial.¹⁷ Even in patients over 65, who have universal access to Medicare, lower income predicts lower trial participation.¹⁷

Aside from cost, there are several patient-specific factors that contribute to a lack of accrual in urologic clinical trials. Often, the clinical trial inclusion/exclusion criteria themselves present decreased opportunities for patient participation. Patients may be excluded from a trial they otherwise would like to join due to comorbidities.¹⁸⁻²⁰

For patients who are eligible for a study, there is often a lack of clinical trial awareness.²¹ Patient surveys report that patients lack an understanding of the trial purpose, as well as knowledge about treatment and trial options.²¹ Additionally, patients may fear the experiment will be prioritized over their health and fear any potential unknown side effects.²¹

Furthermore, many patients distrust the medical system for various reasons, including prior historical, personal, or family experiences. These factors are exacerbated when language barriers are present. Clinical trials often lack culturally relevant education, as well as materials in the patient's native language.²²

Structural barriers

Access to clinical trials through provider referrals is a major barrier to accrual.^{1,23} Many oncology clinical trials are conducted at the NCI or designated cancer centers, including academic centers and select community oncology practices supported by the NCI, yet relatively few cancer patients are treated at these sites.²⁴ According to a report from the American Society of Clinical Oncology, 42% of oncologists work at physician-owned practices, over a third of which do not participate in cancer clinical trials.²⁵ This results in less than half of all cancer patients having access to clinical trials.^{1,24-26}

In a 2016 survey distributed to medical oncologists, the primary reported barriers to oncology clinical trial patient accrual included lack of trial awareness, perceived lack of patient interest, and logistical barriers.²⁷ In a survey of practicing medical and radiation oncologists, logistical barriers included time constraints relating to the trial, such as extra paperwork, patient education, and extended followup clinic visits, as well as timing of events within trials.²⁸

For urologists, many structural barriers exist that prevent their practices from being able to offer clinical

trial referrals to their patients. Credentialing a practice to offer clinical trials often presents large bureaucratic hurdles before referral to trials can even begin. Most clinical trials require a practice to undergo an intensive process to obtain human subject credentialing and make substantial additional investments in learning about trials, opening them in their practice, and conducting extensive data collection. Ellis et al note that this is a particular challenge for community-practicing urologists focused more on providing community access to routine urological services.²¹ Community clinic providers often have a high volume of patients and heavy administrative workload. As a result, community clinic providers often need specific personnel and informational resources to actively refer to a clinical trial.

Community clinics may not have the time or resources to support informational brochures, informational videos, and internet sources when introducing trials.¹⁰ Logan et al show that as a consequence to community cancer providers not being properly engaged in the patient accrual process, patients are introduced to these trials far too late to meet eligibility requirements.⁹

DISCUSSION

Considering the provider, patient, and structural barriers, we propose the following interventions, summarized in Table 2, as well as recommendations to promote clinical research in the field of urologic oncology, summarized in Table 3. Although not addressed in this review, it should be acknowledged that the various cancers within the field of urologic oncology, such as urothelial carcinoma and cancers of the prostate, kidney, testis, and penis, have unique barriers to surgical and medical management and research. Though they share common provider, patient, and structural barriers elucidated below, further exploration of these organ-specific differences represents an opportunity for continued research.

Overcoming provider-level barriers

Ellis et al have shown that small interventions can be done to encourage referral from community providers to those offering clinical trials.²¹ Urologists should receive regular communication from research centers about eligibility status in order for the screening process to not become overly cumbersome. It is recommended that referral for eligibility screening to research centers should take the place of the eligibility screening at the community level.²¹ Ellis et al also outlined the importance of urologists having easy, point-of-care access to flowsheets outlining ongoing trials and their eligibility

criteria in order to increase referrals. It is important for community providers to receive feedback from research centers on research outcomes in order to positively reinforce this working relationship.²¹

This 'dedicated referral pathway' should take place at the treatment counselling visit prior to patients' decision on treatment so that referrals to trials do not take place after treatment decisions have already been made. Research centers should, in turn, work on creating cancer center hotline referral processes for urologists and their patients to call to start the process of trial enrollment once a patient has been identified as potentially eligible at the point of care. These processes can help to develop pathways to cancer centers, which improves clinical trial recruitment while removing overburdensome administrative tasks from community physicians.²¹

Continuing education, for example a 'meet-the-researchers' workshops at professional society meetings, as well as quarterly newsletters, have successfully been implemented in rural urology practices to help increase referral to clinical trials. In-person, face-to-face opportunities to meet trial investigators at society meetings, luncheons, and meet-and-greets helps to familiarize referring urologists with local trials and the faculty/staff running them. This creates a more functional working relationship and promotes trust and improved communication.²¹

Overcoming patient-level barriers

Having cultural and linguistic adaptations of clinical trials' marketing materials can have significant impacts on patient accrual. As Wenzel et al show, having culturally adapted recruitment cards results in increased patient likelihood to enroll in clinical trials and significant increases in actual recruitment rates of under-represented populations. In one example, Asian Americans who received a pan-Asian greeting card mailed with a traditional marketing packet were 4.5 times more likely to enroll than those who were sent a traditional packet alone.²⁹

Heiney et al detail the Heiney-Adams Recruitment Framework (H-ARF), which combines relationship-building and social marketing in order to increase cancer clinical trial recruitment, focusing on under-represented populations. Relationship-building uses person-centered counselling theory to create a more trusting bond between research staff, the patient, and their family. Social marketing involves the use of traditional marketing strategies to influence attitudes in certain target demographics. Under this framework,

Table 3. Summary of recommendations to promote clinical research in the field of urologic oncology

	Recommendation	Study	Impact
Provider-related	Regular communication between clinical trials and community physicians	Ellis et al ²¹	Increase patient referrals from community practices while reducing burden on physicians
	Point-of-care flowsheets	Ellis et al ²¹	Increase patient referrals from community practices while reducing burden on physicians
	Referral hotline	Ellis et al ²¹	Urologists and patients can call to start trial enrollment process
	Continuing education: 'Meet the researchers' workshops, quarterly newsletters, etc.	Ellis et al ¹⁰	Promotes working relationships
Patient-related	Culturally adapted recruitment cards	Wenzel et al ²⁹	Increase recruitment rates of under-represented populations
	Social marketing	Heiney et al ³⁰	Plain language, testimonials from community leaders, and patient quotations increase recruitment
	Patient-centered communication strategy	Green et al ³²	Targeted and empathetic communication strategies led to a 373% increase/11-month period in patient accrual
Structural-related	Branded marketing	Ellis et al ¹⁰	Helps referring physicians initiate conversations about trials and improves patient attitudes
	Use of patient navigators	McClung et al ²²	Improved patient attitudes
	Patient navigation programs	Green et al ³²	Patients enrolled in navigation programs were 4.88x more likely to complete trial
	Engaging patients in community settings	Borno et al ³³	Reduces travel burden, increases accrual
	Telehealth	Baca-Motes et al, ³⁵ Caceres et al, ³⁶ Bobb et al ³⁷	Adapts consent process to shutdowns, lockdowns, and quarantines
	Community partnerships	Petereit et al ³⁸	Establishing trusting partnership with community (e.g., navigators, transportation) led to 96% success rate within 10 months

researchers increased reception of research messaging and advertisements in the community with the use of plain language and other low-literacy principles, trifold brochures that included testimonials from community leaders and patients, newspaper ads featuring human

interest stories, and quotations from patients involved in the project.³⁰

In a real-world example, the above principles were used in a 30-minute NIH cancer education program, which was modified to include African American representation in data and photos. Following this intervention, participants had a more positive perceptions of clinical trials and had a higher likelihood of enrolling in a clinical trial.³¹ This framework is applicable among many different fields of clinical research and shows promise that urologic oncology trials have the potential to increase accrual and improve patient attitudes towards research through the use of culturally attuned, patient-centered marketing materials.

It has been shown that research centers can successfully implement more nuanced and patient-centered communication strategies, like H-ARF, in order to increase patient accrual in clinical trials. In one study aimed at increasing accrual of African American breast cancer survivors, research centers were given instructions to ask about the patient's well-being prior to any discussion about the clinical trial and emphasized a genuine, empathetic, and respectful interaction. In an additional communication strategy, brochures and newsletters were sent to local nail salons, churches, cancer support groups, community events, and universities. As a result, over the 11-month recruitment period, there was a 373% increase in accrual rates for young African American breast cancer survivors, compared to the prior period.³²

Overcoming structural barriers

Another possible intervention for increasing patient accrual is marketing. Offering patients and referring physicians specifically branded patient-facing materials, including brochures, can help with patient accrual for clinical trials.²¹ It not only improves attitudes about specific research projects among patients, it also provides referring community urologists with informative material they can use to engage in conversations about clinical trials with patients. This removes some of the time burden of clinical trial referral for community physicians by presenting them with material that is easily understood by patients. In one trial, urologists at a regional academic conference were offered to participate in clinical trial referrals through a program that used pre-made marketing materials; 61% of urologists presented with the offer asked to be contacted to participate in the program, showing promise that community urologists are a valuable source of clinical trial referrals when research centers can share in the work of patient education and marketing.²¹

Patient navigation programs that reach out directly to potential research participants, rather than referring physicians, have been shown to increase clinical trial recruitment. McClung et al examined the use of bilingual cancer survivors trained as patient navigators in support of Chinese female cancer patients. They recruited 28 breast and gynecologic cancer patients pursuing treatment at Stanford within the Chinese-speaking population and, through the use of patient navigators, improved patient attitudes in four of 10 true-false knowledge statements about clinical trials.²²

Green et al used patient navigators to recruit African American breast cancer survivors for research trials. Of the 378 African American patients who were eligible for clinical trials and referred to patient navigators, 80% enrolled in a trial and 72% consented to receive patient navigation support throughout the trial. Patients enrolled in the patient navigation program were 4.88 times more likely to complete the clinical trial.³²

Using new methods of consenting and accruing patients at sites that are more convenient to patients, as well as engaging community settings in clinical trials, may aid accrual, as travel burden and access to trials have been significant accrual barriers.^{21,33}

The COVID-19 pandemic has added another layer of complexity to clinical trial patient accrual and overall success. Sayyid et al found that of oncology clinical trials put on hold in the first 1.5 years of the pandemic, COVID-19 accounted for 12.2% of these suspensions.³⁴ In the era of shutdowns, lockdowns, and quarantines, telehealth may be used to accrue, consent for, or even run trials, which has proven feasible.³⁵⁻³⁷ In a randomized trial, Bobb et al found that compared to face-to-face consent, telemedicine had similar subjective rates of understanding of consent, as well as accrual rates.³⁷

In addition to being non-inferior, telemedicine may also yield another benefit for clinical trials. By highlighting new technology used in a clinical trial, Baca-Motes et al increased the rate of enrollment from 0.8% to 9.4%. In fact, messaging about new technology proved more successful than messaging about the altruistic benefits of being in a trial and messaging about gaining personal health information.³⁵ This insight will help alleviate, and perhaps increase, structural barriers surrounding patient accrual in clinical trials in the COVID-19 era.

Formal community partnerships between research institutions and local patient populations have also been shown to improve clinical trial accrual. One example is the Walking Forward Program between NCI and American Indian Population in the Northern Plains. This project entailed establishing a trusting partner-

ship between research teams, community hospitals, and American Indians in South Dakota, and resulted in successful recruitment to clinical trials. Visiting the community, employing local tribal members as project staff, and using an American Indian nurse as a patient navigator helped to address socioeconomic barriers by providing transportation, meals, and lodging. This model of using community partnerships allowed researchers to recruit 26 of 27 eligible patients within 10 months.³⁸

CONCLUSIONS

There are many interventions for overcoming the accrual barrier to increase clinical trial accrual. Ultimately, a multidimensional approach that involves inclusive methods for patient recruitment, patient-centered care, navigators, and increasing resources for providers and practices is recommended.¹⁹

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This paper has been peer-reviewed.

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CORRESPONDENCE: Mr. Adam Hass, Zucker School of Medicine at Hofstra/Northwell, Hempstead, NY, United States; ahass12@pride.hofstra.edu