Original Article

Use of a Clinical Trial Screening Tool to Enhance Patient Accrual

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BACKGROUND: Clinical trial patient accrual continues to be challenging despite the identification of multiple physician, patient, and system barriers. Expanded collection of demographic data, including socioeconomic status (employment, income, education) and comorbidities, can enhance our understanding of the identified barriers, inform the development of interventions to overcome these barriers, and recognize their impact on treatment outcomes. A clinical trials screening tool was developed to collect expanded demographic data and barriers to trial enrollment; it has been implemented in the National Cancer Institute Clinical Oncology Research Program. The purpose of this article is to describe the development and implementation of the tool and to share information obtained during the first 43 months of its use. **METHODS:** There were 19,373 entries collected; 74% of those screened enrolled in a clinical trial. Demographic characteristics were compared between those screened and those enrolled. They varied significantly between the groups. **RESULTS:** Reasons for nonenrollment included ineligibility (50%), eligible but declined (47%), eligible but physician declined to offer participation (2%), and eligible but the study was suspended (1%). The most common reasons for ineligibility were failure to meet the protocol-specific stage of cancer, the presence of comorbidities, and the symptom-eligibility score was not met. The most common reason for eligible patients declining participation was that they had no desire to participate in research. **CONCLUSIONS:** The tool provides valuable information about the characteristics of individuals who are screened and enrolled in National Cancer Institute–sponsored trials, as well as about barriers to enrollment in trials. The data also inform protocol development and interventions at the patient, provider, and institutional level. ***Cancer* 2021;0:1-8**. *© 2021 American Cancer Society*.

KEYWORDS: data collection, National Cancer Institute, physician-patient relations.

INTRODUCTION

Clinical research is vital to the development of evidence-based care and the improvement of patient outcomes, though it is dependent on timely clinical trial accrual of patients, which has been a longstanding challenge. This challenge has grown in the setting of increasingly complex trials with more screening procedures, biospecimen collection, complicated trial designs, and burdensome regulatory procedures. Given the crucial role clinical research plays in the advancement of cancer care, there is a pressing need to increase access to and enrollment in clinical trials, particularly for underrepresented populations.

Barriers to enrollment are well established[1-5]; they include patient characteristics, the physician/research team, or health system factors. Barriers vary by cancer type, patient population, trial type and design, and the characteristics/infrastructure of the accruing organization/site. The collection of data that describes the population being screened for a clinical trial and research site–specific barriers can foster the development of tailored interventions to overcome these barriers. Comparing characteristics of individuals screened and not enrolled with those screened and enrolled can identify factors such as age, race, and socioeconomic status that may impact enrollment. In this article, we describe the development and implementation of a screening tool used by the National Cancer Institute Community Oncology Research Program (NCORP) and provide a data analysis of its first years of use.

NCORP,[6] established in 2014, brings state-of-the-art clinical research to community settings. The program includes 46 community sites, 14 of which are designated as minority/underserved sites. The 46 sites have affiliates totaling 997 sites in 43 states, Puerto Rico, and Guam. The sites enroll patients in treatment, screening, prevention, cancer control, and cancer care delivery trials. The teams at NCORP Research Bases develop protocols and provide data management and statistical support for the conduction of trials within the NCORP research network.

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Use of a clinical trial screening tool has been recommended by the American Society of Clinical Oncology (ASCO), the American College of Surgeons' Commission on Cancer, and jointly by ASCO, the American Association for Cancer Research, the American Cancer Society, and the National Cancer Institute (NCI), to address low rates of clinical trial patient accrual.[7,8] A screening tool was used in the NCI's Community Clinical Oncology Program (CCOP), and data from the tool were used to evaluate the first 2 years of the minority-based CCOP. The tool confirmed known barriers: patient ineligibility based on comorbidities, language barriers, financial burdens, logistical issues such as transportation, time off from work, and lack of trust of the health care community.[9] These barriers may be more pronounced today given the overall obesity epidemic, the shift in the U.S. population with the growth in the Hispanic and immigrant populations,[10] complex clinical trials, and prohibitively expensive cancer treatments.

SCREENING TOOL DEVELOPMENT AND IMPLEMENTATION

Screening tools used in the Center for Disease Control's NCI Community Cancer Centers Program (NCCCP)[11] and CCOP, as well as NCORP community sites were reviewed and served as the basis for the development of the screening tool. A small working group consisting of NCORP community-site administrators and NCI staff was formed to provide input on the tool. The final tool includes questions that address gaps in the content of the prior tools and additional questions deemed necessary to address patients' clinical trial enrollment. The tool consists of 44 questions including expanded demographic data and known/published barriers to participation (see Supporting Information). The data are obtained from the participant's medical record and participant interviews. The tool takes less than 5 minutes to complete, although the entire process (consenting, obtaining data, and completing case report form) takes 30 to 45 minutes. Method of diagnosis is included as it is a factor that may influence stage at presentation and treatment outcomes. Comorbidities (hypertension, diabetes mellitus, heart disease, hypercholesterolemia, diabetic neuropathy, other cancers, and nonmalignant systemic disease) are included to document key factors that may impact clinical trial enrollment. Wujcik and Wolffe[12] noted 17% of Black/African American patients cared for at a public urban hospital were ineligible to participate in clinical research because of comorbidities. Langford et al[13] found that Blacks had more physical/medical conditions compared with Whites.

Additional questions were later added either at the request of investigators within NCORP or to address programmatic interests. To better define the minority populations screened, foreign-born status, geographic ethnic group, and primary language spoken at home are included in the tool. Given the impact of tobacco use on treatment outcomes, tobacco-use questions were added. In addition, a question was added to determine if patients had primary care physicians. This information was helpful to NCORP programmatically because the cancer prevention research portfolio requires a partnership with primary care physicians and other nononcology specialists to identify potential research participants of average or high risk of developing cancer.

MATERIALS AND METHODS

A protocol and consent form were developed to collect the screening data. A screened person is defined in the protocol as meeting the following basic eligibility criteria from the parent trial: tumor histology, stage, age, language requirement, and for symptom trials, the required symptom for which the study intervention was intended. All pediatric and adult patients with cancer or at risk of cancer who are being screened for an NCI cancer control, prevention, or late-phase treatment trial within the NCORP Network are invited to participate in the screening protocol.

Following a series of informational webinars, the tool was launched on February 22, 2016. The first participant was enrolled on March 16, 2016. Training materials including step-by-step data entry, all protocol related materials including a list of frequently asked questions (FAQs) are posted on the NCI Clinical Trials Support Unit. All sites are required to implement the tool. Initially, only those patients screened for cancer control and prevention trials and select cancer care delivery studies were included. In May 2017, patients screened for late-phase treatment trials were added, and a separate case report form was designed for pediatric trials.

Statistical analysis was performed using SAS version 9.4.[14] For data included in Table 1, chi-square tests were performed to determine if the distribution of characteristics differed between the enrolled and not-enrolled patients. If the overall chi-square test was significant, individual *t* tests were performed to determine which categories of a characteristic exhibited differences. To illustrate,

TABLE 1. Characteristics of Patients Screened and Enrolled (n = 16,095)

Characteristic	Screened but Not Enrolled (%)	Screened and Enrolled (%)	*P*-value for Difference[a]
All	4193 (26)	11,902 (74)	
Sex			**<.0001**
Female	3170 (76)	9448 (79)	**<.0001**
Male	1020 (24)	2453 (21)	**<.0001**
Unknown	3 (*)	1 (*)	**.0257**
Age, y			**<.0001**
0-8	13 (*)	29 (*)	**.4687**
9-14	3 (*)	20 (*)	**.1549**
15-39	261 (6)	819 (7)	**.1439**
40-59	1600 (38)	5014 (42)	**<.0001**
60-64	596 (14)	1903 (16)	**.0063**
65-70	760 (18)	2074 (17)	**.3062**
>70	960 (23)	2043 (17)	**<.0001**
Marital status			**.0034**
Divorced	610 (14)	1742 (15)	**.8895**
Domestic partnership	69 (2)	243 (2)	**.1096**
Married	2667 (64)	7792 (65)	**.0297**
Never married	403 (9)	1097 (9)	**.4500**
Separated	75 (2)	178 (*)	**.1894**
Widowed	369 (9)	850 (7)	**.0004**
Race			**.0191**
White	3601 (86)	9994 (84)	**.0032**
Black or African American	396 (9)	1197 (10)	**.2531**
American Indian/ Alaska Native	22 (*)	79 (*)	**.3267**
Native Hawaiian/other Pacific Islander	11 (*)	30 (*)	**.9095**
Asian	85 (2)	325 (3)	**.0129**
More than one race	16 (*)	84 (*)	**.0216**
Not reported	62 (1%)	193 (2%)	**.5239**
Unknown			
Ethnicity			**<.0001**
Hispanic or Latino	243 (6)	458 (4)	**<.0001**
Non-Hispanic/Latino	3905 (93)	11,342 95)	**<.0001**
Not reported/unknown	45 (1)	102 (*)	**.2056**
Rural			**.0273**
Yes	832 (20)	2554 (21)	**.0272**
No	3361 (80)	9348 (79)	**.0272**
Education			**<.0001**
No formal education	9 (*)	10 (*)	**.0341**
Grade school	57 (1)	107 (*)	**.0106**
Not high school graduate	222 (5)	469 (4)	**.0002**
High school graduate	1088 (26)	2513 (21)	**<.0001**
Graduate or professional degree	126 (3)	351 (3)	**.8543**
Some college or associate degree	1290 (31)	3850 (32)	**.0588**
Bachelor's degree	858 (20)	2637 (22)	**.0222**
Master's degree	409 (10)	1466 (12)	**<.0001**
Doctoral or professional degree	112 (3)	429 (4)	**.0039**
Not reported	22 (*)	70 (*)	**.6393**
Employment status			**<.0001**
Employed ≥32 h/wk	1447 (35)	4524 (38)	**<.0001**
Employed ≤32 h/wk	363 (9)	1077 (9)	**.4448**
Full-time student	35 (*)	87 (*)	**.5053**
Part-time student	2 (*)	20 (*)	**.0697**
Homemaker	145 (3)	500 (4)	**.0349**
Retired	1599 (38)	4056 (34)	**<.0001**
Unemployed	207 (5)	582 (5)	**.9038**
Only temporarily laid off, sick leave, or maternity leave	38 (*)	73 (*)	**.0487**
On medical leave	116 (3)	301 (3)	**.4050**
Disabled	215 (5)	618 (5)	**.8705**
Unknown	26 (*)	64 (*)	**.5385**
Household income			**<.0001**
<$25,000	658 (16)	1768 (15)	**.1920**
$25,000-$50,000	866 (21)	2342 (20)	**.1736**
$51,000-$100,000	989 (24)	3232 (26)	**<.0001**

TABLE 1. *Continued*

Characteristic	Screened but Not Enrolled (%)	Screened and Enrolled (%)	*P*-value for Difference[a]
>$100,000	684 (16)	2603 (22)	**<.0001**
Patient refused	996 (24)	1957 (16)	**<.0001**
Method of payment for insured	n = 3802 (90%)	n = 8068 (67%)	**.1644**
Private insurance	1890 (50)	4146 (51)	**.0880**
Medicare	466 (12)	922 (11)	**.1897**
Medicare and private insurance	952 (25)	1883 (23)	**.0426**
Managed care/Medicare	79 (2)	134 (2)	**.1103**
Medicaid	228 (6)	539 (7)	**.1573**
Medicaid and Medicare	77 (2)	202 (3)	**.1083**
Veterans sponsored	15 (*)	32 (*)	**.9864**
Military sponsored (including CHAMPUS & TRICARE)	29 (*)	79 (*)	**.2465**

Abbreviations: CHAMPUS, Civilian Health and Medical Program of the Uniformed Services; TRICARE, formerly known as the Civilian Health and Medical Program of the Uniformed Services.
* = <1%.
[a]Bold entries indicate *P*-values for chi-squared test of independence, non-bolded entries represent *P*-values for pairwise t-tests.

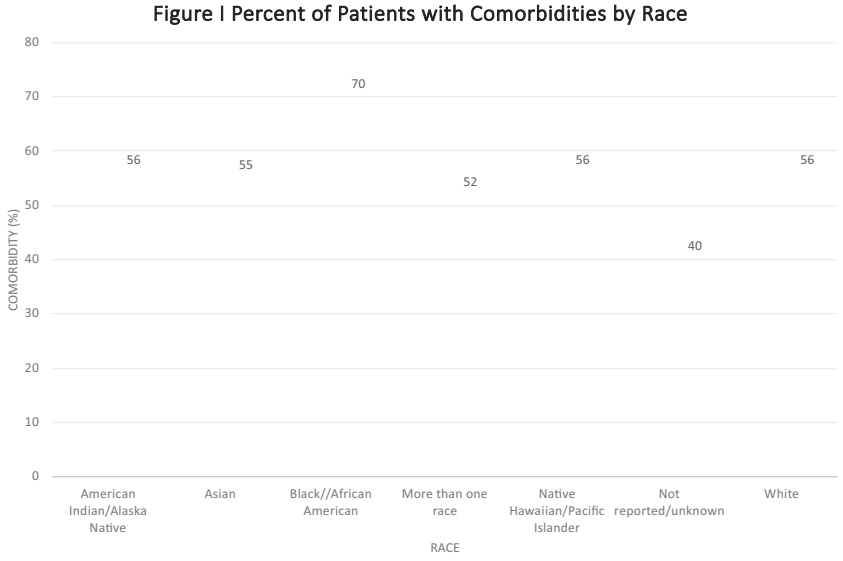

Figure 1. Percentage of patients with comorbidities by race.

the chi-squared *P* value for age was highly significant ($P < .0001$). Subsequent *t* tests suggest the differences were caused by differences in percentages for age groups 40 to 59 years, 60 to 64 years, and >70 years ($P < .0001$, $P = .0064$, and $P < .0001$, respectively).

RESULTS

Data from March 16, 2016 to June 30, 2019 are included in the analysis, which consists of 19,373 entries, of which 16,095 (83%) provided informed consent to participate in the screening tool protocol. Because informed consent was not provided, the reasons patients did not participate in the screening tool were not captured. All 46 NCORP sites activated the protocol with accrual of at least 1 participant from 457 affiliate sites. Of the 16,095 potential trial participants, 11,902 (74%) enrolled in a clinical trial (Table 1). Blacks/African Americans and Native Hawaiians or other Pacific Islanders enrolled at approximately the same overall enrollment rate (75%). Data for American Indians/Alaska Natives, Asians, and individuals of more than 1 race were inconclusive based on small numbers. Seventy-nine percent (9448) of participants enrolled in a clinical trial were female; the median age was 60 years (range, 1-95 years); 65% were married. Of enrolled participants, 21% were rural-based (47% defined

by provider shortages and 53% defined by lack of proximity to cancer care). Most participants (38%) were employed 32 hours or more per week, closely followed by retired (34%). Thirty-two percent of participants had some college or an associate degree, followed by high school degrees (21%). Household income ranged from <$25,000 to >$100,000: 15% <$25,000; 20% $25,000 to $50,000; 27% $51,000 to $100,000, and 22% >$100,000. Sixteen percent declined to provide income data. The majority of participants were insured (68%) with 51% by private insurance; <1% was insured once engaged in the clinical trial enrollment process; and 1% remained uninsured. There were 480 participants (6%) insured via the Affordable Care Act (See Table 1).

Of potential participants, 4193 patients (26%) did not enroll in a clinical trial: 2077 (50%) did not meet trial eligibility; 1973 (47%) were eligible but declined participation; 95 (2%) were eligible but physician declined to offer participation; and 48 (1%) were eligible but the study was suspended.

A chi-square test was performed to determine if the distribution of characteristics (Table 1) differed between the "enrolled" and "not enrolled" populations. All characteristics were clinically significant with the exception of method of payment ($P = .1644$). The differences in race were driven by the differences in Whites, Asians, and those of more than 1 race. The differences in age were seen in those 40 years and older. The most significant difference in marital status was seen in married individuals, and to the greatest degree in widowed individuals. Significant differences were seen in education with the exception of those with graduate or professional degrees. There were no differences in those who were employed <32 hours per week, students, unemployed, on medical leave, or disabled. The most significant differences in household income were seen in individuals with levels >$50,000. There was no difference between the 2 groups with income levels <$25,000 and $25,000 to $50,000. The only methods of payment that were significant between the groups were those insured with Medicare and private insurance. Reasons for ineligibility are outlined in Table 2. The most common reasons for ineligibility included inappropriate stage, symptom eligibility score was not met, and trial prohibited concurrent disease condition. Examples of other reasons included patients' current or past activities or medications conflicting with the intervention arm (yoga, exercise program, taking aspirin), insufficient tissue for diagnostic testing, not enough time to complete trial assessments, and inability to reach patient. One commonly documented reason for ineligibility, abnormal labs/tests, accounted for only 4% of the reasons. Reasons eligible patients declined enrollment accounted for 47% (Table 3). The most common reasons included the patient had no desire to participate in research (29%) and the patient preferred another treatment (27%).

More Blacks/African Americans (70%) than Whites (56%) reported having a comorbidity (Fig. 1). The most frequently occurring comorbidity was hypertension in Blacks/African Americans, followed by diabetes mellitus in American Indians or Alaska Natives and hypercholesterolemia in Asians (Table 4). Comorbidities increased with age (Fig. 2). The most

TABLE 2. Reasons Patient Did Not Meet Trial-Eligibility Criteria[a]

Not eligible	N = 2259 (%)
Other	320 (14%)
Failure to meet protocol-specific stage of cancer	320 (14%)
Trial prohibited concurrent disease/condition (comorbidities)	310 (14%)
Symptom eligibility score not met	306 (14%)
Prohibited treatment/medicine	189 (8%)
Did not meet biomarker testing criteria	152 (7%)
Timing of current or prior treatment	151 (7%)
Patient unwilling or unable to comply with eligibility criteria	108 (5%)
Inappropriate histology	106 (5%)
Inappropriate surgical margin	91 (4%)
Abnormal labs/tests	85 (4%)
Already started treatment	47 (2%)
Performance status	37 (2%)
Age outside eligible range	23 (1%)
Patient unwilling or unable to provide informed consent	14 (<1%)

[a]Includes more than one response per individual.

TABLE 3. Reasons Eligible Patients Declined Participation[a]

Reason	N = 1995 (%)
No desire to participate in research	573 (29%)
Patient preferred another trial or treatment	533 (27%)
Other	173 (9%)
No time	127 (6%)
Preferred not to do additional testing/paperwork	115 (6%)
Overwhelmed/fatigued	113 (6%)
Social issues (housing, childcare, etc.)	108 (5%)
Perceived side effects/toxicities too great	80 (4%)
Excessive financial burden (e.g., lost wages, excessive out of pocket expenses/copayments)	56 (3%)
Insurance issues	53 (3%)
Did not want to delay treatment	30 (1%)
Did not return to institution	22 (1%)
Caregiving issues	12 (<1%)

[a]Includes more than one response per individual.

TABLE 4. Comorbidities by Race

Race	Hypertension No. (%)	Diabetes Mellitus No. (%)	Hypercholesterolemia No. (%)	Other Nonmalignant Issues No. (%)	Other Cancer Within 5 y No. (%)
American Indian or Alaska Native	37 (37%)	26 (26%)	16 (16%)	7 (7%)	4 (4%)
Asian	149 (36%)	66 (16%)	106 (26%)	39 (10%)	9 (2%)
Black or African American	908 (57%)	337 (21%)	332 (21%)	192 (12%)	60 (4%)
Native Hawaiian/Pacific Islander	11 (27%)	7 (17%)	6 (15%)	6 (15%)	0 (0%)
White	4883 (35%)	1652 (12%)	3191 (23%)	1637 (12%)	746 (5%)
More than one race	41 (41%)	13 (13%)	22 (22%)	11 (11%)	5 (5%)
Not reported/unknown	64 (25%)	37 (15%)	31 (12%)	14 (5%)	10 (4%)

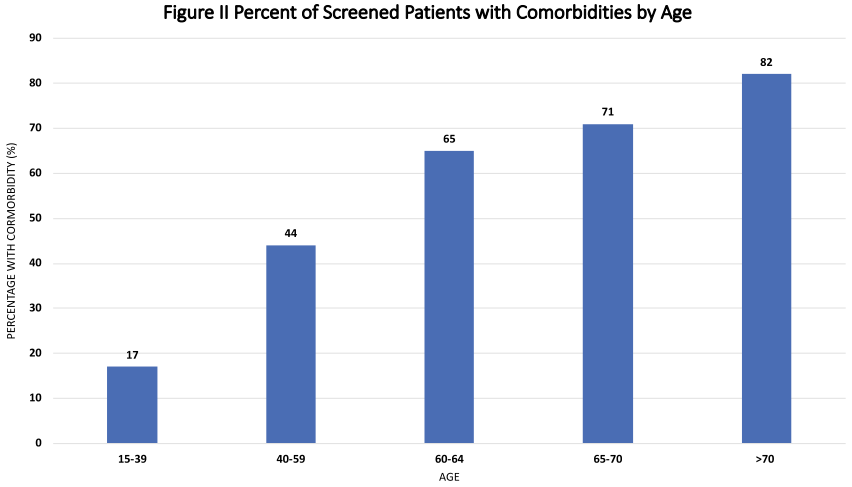

Figure 2. Percentage of screened patients with comorbidities by age.

common comorbidities in individuals age ≥70 years included hypertension, followed by hypercholesterolemia and diabetes mellitus.

The percentage of patients who enrolled in a clinical trial across the network did not vary among community sites, minority/underserved community sites, and sites designated as high performers (73%, 75%, and 74%, respectively). Among 6038 screened, 79% reported having a primary care physician and nearly half (2325 of 4747) of those enrolled in a trial had a primary care physician.

Overall, the use of this screening tool has proven feasible and has been successfully implemented in NCORP. The expanded data has provided an opportunity to characterize those screened and analyze variables that may impact enrollment—and ultimately treatment outcomes. Furthermore, understanding protocol and site-specific barriers informs tailored interventions to enhance patient accrual, particularly for underrepresented populations.

The tool showed a high clinical trial enrollment rate of 74%. Notably, Blacks/African Americans and Native Hawaiians or other Pacific Islanders enrolled at approximately the same overall enrollment rate (75%). This is consistent with the literature. Langford et al[13] noted no racial differences in clinical trial accrual, refusal rates, and desire to participate in research within the NCCCP. The majority of individuals enrolled were female (79%), which is likely related to the trials included in the screening tool, one of which is a large breast cancer screening trial. The tool did not capture trial availability, which is an important consideration when evaluating clinical trial enrollment. This would inform the gaps in research for certain tumor types. Unger et al[15] noted that a trial was not available 55.6% of the time when 13 studies were analyzed using a conceptual framework to characterize treatment decision making for trial participation.

Our data reflected that in the literature regarding barriers to clinical trial enrollment such as age, race (as noted above), income, method of payment, and comorbidities. For all age categories, the screened to enrollment rate was either the same or a greater except for individuals aged >70 years (P for difference < .0001). Sedrak

et al[16] reported on a systemic review of 13 studies that examined barriers to enrolling older adults in clinical trials. No new barriers emerged; however, only 1 of the 13 articles focused on an intervention showing a high need for intervention studies to address barriers in this patient population.

Individuals with household income levels >$50,000 were more likely to enroll in a trial than not ($P < .0001$). There was no difference in individuals enrolled versus not enrolled with income levels <$25,000 and $25,000 to $50,000 ($P = .1920$ and $P = .1736$, respectively). Slightly over a third of our sample (35%) had annual household incomes of ≤$50,000. Unger et al[17] reported that most people with lower incomes were less likely to participate in clinical trials. Our data showed that patients with private insurance experienced the highest rates of enrollment. Comparison of those individuals screened and not enrolled to those screened and enrolled demonstrated that the only method of payment that showed a significant difference ($P = .0426$) between the groups was combined Medicare and private insurance. Unger et al[18] showed that clinical trial participants with Medicaid experienced worse treatment outcomes when compared with participants with private insurance.

Chronic and acute comorbidities have been documented as a barrier to clinical trial accrual of patients, particularly for racial/ethnic minorities and older adults. Our data showed the highest level of comorbidities among African Americans and individuals over the age of 70 years. In a survey conducted by Unger et al,[19] patients with 1 comorbidity or more were less likely to discuss clinical trials with their physician, less likely to be offered participation in a trial, and less likely to participate in a trial. ASCO, Friends of Cancer Research, and the NCI recently developed guidelines to broaden eligibility criteria for patients with preexisting conditions.[20] However, this does not address the barrier of accruing indivduals with chronic comorbidities, such as diabetes mellitus, hypertension, and other cardiovascular diseases. Co-management of these comorbidities with primary care providers or other specialists while the patient is in a clinical trial should be explored. Cohorts of these patients could be accrued to a trial and guidelines for management could be tested as part of a correlative study.

Of those patients eligible to participate, 49% did not enroll. The most frequent reasons included no desire to participate in research and preference for another treatment, including standard of care. The percentage of patients who cited other reasons, such as time, social issues, perception that toxicities were too great, and financial burden, ranged from 3% to 6%. It was not uncommon for individuals to identify more than 1 reason. There is an opportunity for patient education regarding clinical trials and the benefits of being enrolled in a trial. It is critical that patients' decisions are informed and that misperceptions of toxicity burden or concerns regarding being a test subject are allayed. The subject of culture and health literacy, information that is currently collected, is a topic of future study, given the ever-changing and increasingly diverse population of the United States. Though socioeconomic status data have been identified as an important variable for clinical trial participation, it is often not collected. However, it is important given that cost has been identified as a barrier to treatment: Patients with lower income are less likely to participate in research.[17] The collection of these data within a community setting has been demonstrated in this study.

Our data did not uncover barriers that were not previously identified in the literature. Nevertheless, the tool uniquely identifies barriers by protocol. This information has been used by investigators to determine if any changes can be made to enhance patient accrual. For example, the primary reason participants refused to participate in a trial focused on the older adult population was the number of questionnaires/patients' reported measures. The investigator was able to take a look at the timing and volume of the assessments and make adjustments to decrease the burden on patients. Barriers can also be analyzed by patient characteristics such as age, race, socioeconomic status, and comorbidities.

The NCORP sites can access their own site data, though this has occurred less often than anticipated. It was thought that the sites would use the data to determine staffing needs for screening activities, to understand the types of trials they will successfully accrue to, and to understand the characteristics of the population within their catchment area. It is paramount that the data generated from the tool are useful to the research sites and investigators. We will seek input from them to determine the aspects of the tool they find most useful. Considerations under discussion for additional data elements include sexual orientation/gender identity, additional social determinants of health, and family history. We plan to disaggregate the ethnicity category to provide a greater understanding of Hispanic populations.

As of October 2020, the screening tool had over 29,000 entries. Use of the tool continues to be strong even during the COVID pandemic. The tool has been very useful during this critical time to understand the sites' capacity to screen patients, document trends in

screening activity, and evaluate the demographics of those entering trials during the pandemic.

Integrating an additional step into the normal workflow of the clinical research team can be challenging; however, we included several approaches to ease site burden. Sites can enter patients into the screening tool's database at the time they consent to join a clinical trial or enroll in the screening protocol within 4 weeks from the time it was determined the patient was eligible or enrolled in the parent trial. Phone consent is allowed, which also has afforded the sites some flexibility. The case report form is electronic and input into the Oncology Patient Enrollment Network (OPEN), the same system used to capture data for all NCI-supported clinical trials. Finally, the groups using the tool receive funding. They also share best practices within NCORP regarding their approach to integrate the tool into their research practices.

The screening tool data are used by NCI programmatically and by investigators and research sites within the NCORP (see Supporting Information). NCI uses these data to evaluate sites' screening efforts and to understand the reasons for languishing accrual by trial. The data are also used to fulfill queries from NCI leadership regarding populations that are screened and accrued to trials.

The screening tool has generated data used by all stakeholders in the NCORP network including research sites and investigators, as well as the NCI. Data captured by the tool can inform the design of future clinical trials and the development of tailored interventions to enhance enrollment.

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CONFLICT OF INTEREST DISCLOSURES

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AUTHOR CONTRIBUTIONS

Diane C. St. Germain: Conceptualization, data analysis, methodology, and writing–editing. **Worta McCaskill-Stevens:** Conceptualization, data analysis, methodology, writing–editing, approval.

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