

# Cancer clinical trial enrollment of diverse and underserved patients within an urban safety net hospital

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**Background** Enrollment rates onto cancer clinical trials are low and reflect a small subset of the population of which even fewer participants come from populations of racial or ethnic diversity or low socioeconomic status. There is a need to increase enrollment onto cancer clinical trials with a focus on recruitment of a diverse, underrepresented patient population.

**Objective** To use the electronic medical record (EMR) to understand the eligibility and enrollment rates for all available cancer trials in the ambulatory care setting at an urban safety net hospital to identify specific strategies for enhanced accrual onto cancer clinical trials of diverse and underserved patients.

**Methods** A clinical trial screening note was created for the EMR by the clinical trials office at an urban safety net hospital. 847 cancer clinical trial screening notes were extracted from the EMR between January 1, 2010 and December 31, 2010. During that time, 99 cancer trials were registered for accrual, including clinical treatment, survey, data repository, imaging, and symptom management trials. Data on eligibility, enrollment status, and relationship to sociodemographic status were compared.

**Limitations** This is a single-institution and retrospective study.

**Conclusion** The findings demonstrate that a formal process of tracking cancer clinical trial screens using an EMR can document baseline rates of institution-specific accrual patterns and identify targeted strategies for increasing cancer clinical trial enrollment among a vulnerable patient population. Offering nontreatment trials may be an important and strategic method of engaging this vulnerable population in clinical research.

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Cancer clinical trials are essential to the progress of optimizing cancer care outcomes. Low enrollment of adult patients onto cancer clinical trials has been a long-standing problem in the United States, with accrual rates ranging from less than 2% to 11%.<sup>1-8</sup> Of those patients who do enroll, most are white, educated, and have a high socioeconomic status as measured by employment, income, and/or insurance status.<sup>7-9</sup> There remains an underrepresentation of diverse and/or underserved participants in cancer clinical trials.<sup>6,9-12</sup> In this article, diverse refers to individuals who self-identified in the electronic medical record as black, Hispanic, Asian or other. Consequently, the findings from cancer treatment trials have questionable generalizability to underserved populations.<sup>2,4</sup> Furthermore, underrepresentation of diverse or socioeconomically disadvantaged populations has resulted in sig-

nificant gaps in knowledge concerning the health beliefs, behaviors, and symptoms of racial and ethnically diverse populations across the cancer care spectrum.<sup>13-15</sup>

Recruitment of diverse populations onto clinical trials has been well studied. Findings from multiple published studies have demonstrated multifactorial and institution-specific reasons for low accrual among diverse populations.<sup>16,17</sup> These findings vary among different patient populations, ambulatory care settings, and delivery systems, suggesting that barriers to equitable accrual are community specific. Moreover, most research has focused largely on cancer treatment trials, with a paucity of research exploring accrual to all types of cancer clinical trials, such as survey or symptom management trials.

Therefore, combining relevant published knowledge with institution-specific characteristics may

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provide specific opportunities to improve accrual.<sup>18</sup> The electronic medical record (EMR) has great potential to aid in this regard, particularly in the setting of the Affordable Care Act and Meaningful Use.<sup>19</sup> The purpose of this study was to use data from EMR screening logs at our ambulatory care clinic to define baseline eligibility and enrollment rates for all cancer trials. Our overarching goal was to identify specific strategies for enhanced accrual onto cancer clinical trials of diverse and underserved patients.

## Methods

We conducted a retrospective study by using patient-level data from EMR (GE Centricity) in the calendar year 2010 to assess eligibility and enrollment characteristics of patients screened for available cancer clinical trials by certified clinical trial nurses in accordance with protocols adopted by the Boston Medical Center (BMC) Clinical Trials Office.

### Study site

BMC is the largest safety net institution in New England and has historically served the city of Boston's poorest and most disadvantaged populations. The BMC Cancer Center is accredited by the American College of Surgeon's Commission on Cancer and serves about 1,300 cancer patients annually, most of whom come from underserved populations, including low-income families, people with disabilities, elders, minorities, and immigrants, regardless of insurance or ability to pay. The BMC–Boston University Medical Campus institutional review board (IRB) approved this descriptive study.

### Study population

Patients who were screened for a cancer clinical trial by trained nursing staff in the BMC clinical trials office and who had documentation of the screening within the EMR between January 1, 2010 and December 31, 2010 were included. Notable exclusions were patients who were screened but did not have specific documentation (see *Study methods* section).

The clinical trials office has several clinical trial nurses who are directly responsible for the open and pending clinical trials in a specific disease subspecialty (eg, breast, lung, gastrointestinal). These clinical trial nurses track and follow new and existing patients within their subspecialty by attending tumor boards, scanning specific provider clinics, and working with the cancer registry. They screen patients for any open trial for which they are potentially eligible.

In calendar year 2010, there were 99 cancer clinical trial protocols either opened or pending IRB approval. These trials are sponsored by a variety of organizations, including the National Cancer Institute (NCI), Southwest Oncology Group (SWOG), Radiation Therapy Oncology Group

(RTOG), Cancer Trials Support Unit (CTSU), AIDS Malignancy Consortium (AMC), American College of Surgeons Oncology Group (ACOSOG), the National Surgical Adjuvant Breast/Bowel Project (NSABP), an industry sponsor, or they are investigator initiated (opened at our institution by one of our investigators). The types of trials available included: treatment, survey, data repository, imaging, and symptom management.

### Study methods

To document and track screening for cancer clinical trials in our ambulatory care setting, the BMC clinical trials program designed a specific template within the EMR for use by the clinical trials nurses. The screening note provides standard fields for:

- Information about the trial for which a patient is being screened for;
- Eligibility status;
- Enrollment status;
- Reasons the patient was or was not eligible; and
- Reasons the patient was or was not enrolled in that trial.

The cancer clinical trial screening note is based on available information at the time the note is created in the EMR.

Clinical trial nurses identified possible eligible patients through several mechanisms: oncology clinic patient visits, multidisciplinary tumor boards, tumor registries, and/or physician referrals. As patients were identified, the clinical trial nurse initiated a screening note in the EMR that documented their possible eligibility and enrollment into specific open clinical trials. Screening notes were not routinely generated when the initial assessment concluded that there were no open trials relevant to that patient's overall disease type. For example, if a new patient was evaluated for a trial enrolling hormone-positive breast cancer cases, yet the pathology reported triple-negative breast cancer, then the patient was immediately considered to have no open trial available and thus no screening note was created. This practice varied among clinical trial nurses, most entered a note documenting "No open trial available," but other nurses entered notes only after learning that other nurses were documenting in that fashion. Patients could be screened for multiple trials, which resulted in multiple screening notes per patient.

### Data collection

All clinical trial screening notes opened within the 2010 calendar year were retrieved from the EMR. When eligibility or enrollment status was missing and/or screenings were deemed ineligible for an open trial, a manual chart abstraction was conducted to determine the exact reason or reasons for the patient's ineligibility and nonenrollment. Documented reasons for ineligibility and nonenrollment

were categorized and described. The study team reviewed all of the findings to agree on final interpretations. Enrollment status was verified through the clinical trials office enrollment database. Sociodemographic variables were retrieved from the electronic registration database, from a predefined list of self-reported categories for race/ethnicity, employment status, primary spoken language, country of birth, primary health insurance, highest level of education, and marital status.

### Study measures

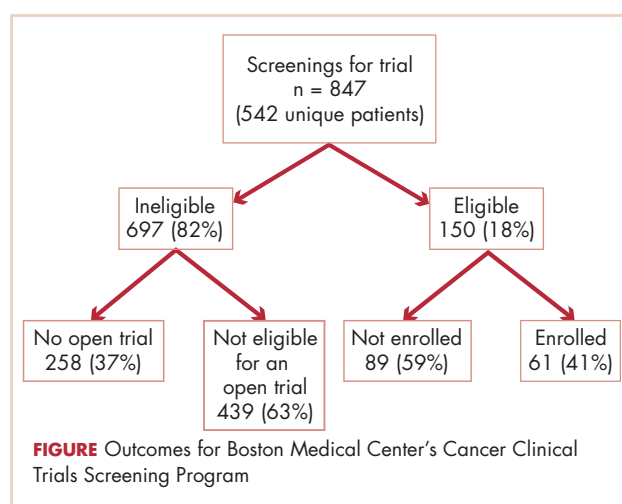
Eligibility status for each screening was categorized as either eligible or ineligible. Ineligible patients were further characterized for the reason ineligible: No Open Trial meant there was no specific trial currently open for the overall disease type, which included administrative reasons for ineligibility for a specific trial (IRB pending and/or trial subset closed); and Not Eligible for Open Trial meant that something specific regarding their disease characteristics made them ineligible for enrollment onto a specific open trial (ie, previous treatment, comorbidity, or missing clinical information). Enrollment status, among those deemed eligible, was categorized as either Enrolled or Not Enrolled. Those who were not enrolled were further characterized for the reason not enrolled (ie, patient declined, or provider preference).

### Analyses

Our unit of analysis was the screening note, not the patient. Patients were included more than once if they were screened for multiple trials. Outcomes of interest included: eligibility rate (number of screens deemed eligible for a specific trial/total number of screens documented), enrollment rate (number who enrolled into a specific trial/ number of screens deemed eligible for a specific trial), and reasons for lack of enrollment. Chi-square and *t* tests were used to compare eligible screens with ineligible screens and enrolled with not enrolled patients in association with sociodemographic variables.

### Results

In 2010, there were 847 screening notes opened among 542 unique patients. That resulted in an average of 2 screens per unique patient (range, 1-7). Most of the urban patients in this diverse group who were screened for trial enrollment were women and majority black (40%); 22% were non-English speakers, and 30% had been born outside of the United States (Table 1). They were predominately covered by public insurance (66%) and either unemployed (31%) or retired (35%); most had breast, lung, or genitourinary cancers; and more than half were screened for a clinical treatment trial (55%), followed by symptom management trials (16%).



The sociodemographic differences in eligibility status were not significant, with the exception of age (Table 1). Ineligible screens were slightly older, with a mean age of 62 years compared with 59 years for the eligible screens ( $P = .012$ ). There were no differences in eligibility status based on cancer site or type of trial (Table 1).

Most of the screening notes ( $n = 697$ , 82%) deemed the patient ineligible (Figure). Among those who were ineligible, about a third ( $n = 258$ ) were ineligible because there was no open trial relevant for that patient either because no trial existed for the specific disease or an existing trial had been suspended owing to administrative issues, such as pending IRB approvals; or because the trial group closed a specific subset (eg, age 40-45 years) to enrollment. The remaining 63% of patients were ineligible because they did not meet specific trial eligibility criteria for a trial actively open for accrual (Table 2). Of the total 847 screenings, 18% (150) were deemed eligible for enrollment onto a clinical trial, and of those 150 eligible, 41% (61) ultimately enrolled.

The most common reason for ineligibility among the group with an available open trial was that disease stage criteria were not met (30%; Table 2). Treatment status was the second most common reason (23%), because some patients had prior chemotherapy or other treatment-related exclusion criteria. Next, missing clinical information (eg, needs CT scan, awaiting staging or other more complete diagnostic testing) accounted for 17%, and comorbid conditions such as renal failure, heart disease, or a second cancer accounted for 15%. Ineligibility based on comorbid conditions primarily occurred when screened for treatment trials, but were equal among white and black patients (44% and 45%, respectively). Ten percent of ineligibility was based on nonclinical criteria not being met, for example, patients who were nonsmokers were not eligible for a trial investigating smokers. Few patients were lost to follow-up (3%) or left the institution to pursue their treatment (2%).

**TABLE 1** Sociodemographics and characteristics of the diverse group of urban patients screened for available cancer clinical trial enrollment (N = 847)

Demographic/ characteristic	Total	Eligible, n (%) (n = 150)	Ineligible, n (%) (n = 697)	P value
Mean age, y	61	59	62	.012
<b>Sex</b>				
				0.98
Female	513 (61)	91 (61)	422 (61)	
Male	334 (39)	59 (39)	275 (39)	
<b>Race</b>				
				0.47
Black	335 (40)	66 (44)	269 (39)	
White	376 (44)	60 (40)	316 (45)	
Hispanic	77 (9)	15 (10)	62 (9)	
Asian	28 (3)	6 (4)	22 (3)	
Other <sup>a</sup>	31 (4)	3 (2)	28 (4)	
<b>Employment Status</b>				
				0.38
Employed	174 (21)	30 (21)	144 (22)	
Unemployed	254 (31)	52 (36)	202 (30)	
Retired	287 (35)	43 (30)	244 (37)	
Disabled	97 (12)	19 (13)	78 (12)	
<b>Language</b>				
				0.85
English	663 (78)	118 (79)	545 (78)	
Spanish	58 (7)	11 (7)	47 (7)	
Other	74 (9)	14 (9)	60 (9)	
Haitian Creole	52 (6)	7 (5)	45 (6)	
<b>US born</b>				
	559 (66)	94 (63)	465 (67)	0.20
<b>Insurance</b>				
				0.53
Public	560 (66)	93 (63)	497 (68)	
Private	204 (24)	39 (26)	165 (23)	
Uninsured	82 (10)	17 (11)	65 (9)	
<b>Education</b>				
				0.84
HS grad	218 (26)	35 (23)	183 (26)	
Less than HS	179 (21)	35 (23)	144 (21)	
More than HS	113 (13)	20 (13)	93 (13)	
<b>Marital status – married</b>				
	333 (40)	69 (46)	264 (38)	0.06
<b>Type of cancer</b>				
				0.5
Brain/CNS	20 (2)	4 (3)	16 (3)	
Breast	315 (38)	46 (31)	269 (40)	
Gastrointestinal	67 (8)	15 (10)	52 (8)	
Genitourinary	112 (13)	18 (12)	94 (14)	
Head and neck	62 (7)	14 (10)	48 (7)	
Lung	218 (26)	44 (30)	174 (26)	
Other <sup>b</sup>	53 (6)	9 (6)	44 (6)	
<b>Protocol type (n = 589)<sup>c</sup></b>				
				0.45
Treatment	322 (55)	75 (50)	247 (56)	
Symptom management	91 (16)	22 (15)	69 (16)	
Imaging	78 (13)	21 (14)	57 (12)	
Survey	60 (10)	19 (13)	41 (9)	
Data repository	38 (6)	13 (9)	25 (6)	

n, number of screens; HS, high school; CNS, central nervous system

<sup>a</sup>Asian or self-identified in the electronic medical record as Other. <sup>b</sup>Sarcoma, melanoma, other. <sup>c</sup>When no trial was available, there was not a protocol type.

Among those patients deemed eligible for a specific trial (n = 150), a total of 61 (41%) enrolled onto the trial, and 89 (59%) did not enroll. Most of those who enrolled were sociodemographically underrepresented and included: 48% diverse; 56% with public insurance; 70% retired, unemployed or disabled; and 54% with a high-school education or less (Table 3). Compared with the patients who enrolled, those who did not enroll were more likely to be diverse than white (68% vs 48%, respectively,  $P < .03$ ) and unemployed, retired, or disabled (87% vs 70%,  $P < .05$ ), and be recruited to a breast trial or a treatment trial.

Documented reasons for nonenrollment of eligible patients were primarily related to patient preference (75%; 67 of 89 declined to participate; Table 4). More specific rationale was not documented. The treating physician deemed a small number of eligible patients (17%) to be noncandidates because of their patient characteristics or treatment needs. Eight percent of those who did not enroll did not have any documentation to explain the reason for nonenrollment.

## Discussion

This retrospective study leveraged the ambulatory care electronic medical record to understand our site-specific cancer clinical trial accrual patterns to inform programmatic interventions geared toward increasing overall enrollment. The lack of diverse participation onto cancer clinical trials has been a long-standing problem. Research and efforts continue to call for understanding of patient and institution specific barriers to diverse enrollment into clinical trials.<sup>11</sup> Specifically, there has been an increased focus and effort on recruitment of diverse populations at the institutions where they receive care.<sup>20,21</sup> Our



**TABLE 2** Reasons for patient ineligibility when screened for an available open cancer clinical trial (N = 439)

Reason	Frequency (n, %)
Disease-stage criteria not met	133 (30)
Treatment status	103 (23)
Missing clinical information	73 (17)
Comorbid conditions	64 (15)
Nonclinical criteria not met	45 (10)
No follow-up documented	12 (3)
Treatment at other institution	9 (2)
<b>Total</b>	<b>439</b>

study answers this call for analysis of our accrual patterns<sup>22</sup> and sharing of our methods and findings.

First, our results define sociodemographic patterns to clinical trial enrollment at our institution, confirming that we screen a diverse, at-risk population for which sociodemographic characteristics did not determine eligibility status. Most of our patients were diverse (56%), had public or no insurance (76%), and were not employed (79%). Among our diverse set of patients, we did not find that sociodemographic differences affected eligibility. These findings are in contrast to those of other studies, which have shown racial differences in eligibility at other institutions.<sup>1,23</sup> Our results are encouraging because they suggest that our clinical trials program is opening types of trials for which our diverse patients are equally eligible.

Second, our results are consistent with a well-known challenge in clinical trial accrual to be the lack of specific, relevant trial availability at any given time.<sup>1,19</sup> Our documented eligibility rate of 18% is largely driven by a lack of open trials that fit patient disease characteristics at the time of screening or, even when patient disease characteristics met open trial criteria, because the trial was not available as a result of administrative barriers such as IRB approvals or trial group subsets being closed (38%, or 97 of 258). These reasons underscore the universal difficulty in maintaining access to costly, open clinical trials that match an institution's specific patient profile at any given point in time,<sup>24</sup> yet suggest several opportunities for improvement.

Simple access and matching trials to the most common disease stages and types observed in our diverse population is critical to increasing our eligibility rate and emphasizes the need for access to relevant clinical trials for our diverse population.<sup>25</sup> This highlights the need to acquire and offer trials, which target questions for our specific patient population.<sup>23,26,27</sup> For example, if our breast cancer patients tend to present within a certain age range, or at a later stage, we can target trials that match those characteristics. Making

**TABLE 3** Characteristics of eligible screenings by enrollment status (N = 150)

Demographic/characteristic	Enrolled (n = 61)	Not Enrolled (n = 89)	P value
Mean age, y	58	60	.2
Sex			
Female	34 (56)	57 (64)	.30
Male	27 (44)	32 (36)	
Race			
Black	23 (38)	43 (48)	.03
White	32 (52)	28 (31)	
Other <sup>a</sup>	6 (10)	18 (20)	
Employment status			
Employed	18 (31)	12 (13)	.052
Unemployed	16 (28)	36 (42)	
Retired	15 (26)	28 (33)	
Disabled	9 (16)	10 (12)	
Unknown	—	3 (3)	
Language			
English	51 (84)	67 (75)	.22
Other	10 (16)	22 (25)	
US born			
Yes	40 (66)	54 (61)	.54
No	19 (31)	34 (38)	
Unknown	2 (3)	1 (1)	
Insurance			
Public	34 (56)	59 (67)	.16
Private	21 (34)	18 (20)	
Uninsured	6 (10)	11 (13)	
Unknown	—	1 (1)	
Education			
Less than HS	13 (21)	22 (25)	.04
HS grad	20 (33)	15 (17)	
More than HS	10 (16)	10 (11)	
Unknown	18 (30)	42 (47)	
Marital Status			
Married	26 (43)	43 (48)	.51
Not Married	35 (57)	46 (52)	
Type of cancer			
Brain/CNS	2 (3)	2 (2)	.0095
Breast	13 (21)	33 (37)	
Gastrointestinal	7 (11)	8 (9)	
Genitourinary	4 (7)	14 (16)	
Head and neck	10 (16)	4 (4)	
Lung	18 (30)	26 (29)	
Other <sup>b</sup>	7 (11)	2 (2)	
Protocol type (n = 589)			
Treatment	23 (38)	52 (58)	.0051
Symptom management	9 (15)	13 (15)	
Imaging	8 (13)	13 (15)	
Survey	10 (16)	9 (10)	
Data repository	11 (18)	2 (2)	

n, number of screens; HS, high school; CNS, central nervous system

<sup>a</sup>Asian or self-identified in the electronic medical record as Other. <sup>b</sup>Sarcoma, melanoma, other.

**TABLE 4** Reasons eligible screenings were not enrolled onto a clinical trial

Reason not enrolled	Frequency, no. of patients (%)
No follow-up documented	7 (8)
Patient declined	67 (75)
Physician preference	15 (17)
<b>Total</b>	<b>89</b>

relevant types of trials available is critical to increasing enrollment, as our data demonstrate that when eligible, a large proportion of patients agree to participate.

In addition to targeting and maintaining trials that are reflective of our patient population, our data provides evidence that there are other immediate opportunities for improving our understanding of the barriers to accrual at our institution. Several of the documented reasons (Table 2) are possibly modifiable, such as:

- Improving ongoing use of the EMR to monitor the most common disease type and stages seen at our institution (ie, disease stage criteria or treatment status) so that relevant trials are chosen to open for accrual;
- Developing a standardized protocol for entry of screening notes into the EMR (eg, no follow-up documented);
- Using more detail to enhance our documentation of reasons for patient refusal; and
- Improving coordination of care to gather relevant clinical information between all oncology care providers expeditiously (eg, missing clinical information).

Furthermore, other published studies that specifically examined treatment trials have suggested that comorbid conditions affect eligibility onto clinical trials, particularly in underserved populations.<sup>1,5</sup> We did not find comorbid medical conditions to play a major role in the eligibility of our patients to our particular set of open trials (both treatment and nontreatment). Only 15% of the screening notes (64 of 439) listed comorbid conditions as the reason for ineligibility, and they were equally distributed between racial/ethnic groups. However, 42 of those 64 ineligible screens due to comorbid conditions were being screened for a treatment trial, suggesting that consistent with the literature, comorbid conditions remain an issue for accruing otherwise eligible participants to treatment trials.

In addition, in contrast to published literature,<sup>1,28</sup> we did not find racial/ethnic differences in trial eligibility. However, consistent with findings in other studies,<sup>10</sup> we did confirm that among our patients who were eligible for trials, diverse and underinsured patients were least likely to enroll. Once eligible, when given the choice of participating in a clinical trial, 41% of individuals from our diverse population enrolled, however, our data does show enrolled

subjects are more likely to be white, employed, and choosing nontreatment trials. Future collection and understanding of the reasons for declining enrollment will be critical data to collect as we pursue steps toward improved accrual.

Unique to our study is the inclusion of nontreatment cancer clinical trials (ie, data repository trials, supportive care trials, surveys), and a demonstration that our patients tend to enroll onto these trials over treatment trials. Recent research has started to acknowledge and address the opportunity to consider the spectrum of trials for which patients may be more willing to participate. For example, Nickell and colleagues have reported on using a “neutral, nontrial-specific” approach to educating and recruitment of breast cancer patients who are of low-socioeconomic status.<sup>29</sup> In addition, Green and colleagues directly addressed the need for high-quality clinical and behavioral research studies, such as a health research registry.<sup>30</sup> This is a distinct option for engaging diverse populations in research. Furthermore, Heller and colleagues have reported that the greater the risk of the intervention (ie, drug trials), the greater the need to develop multiple strategies for recruitment.<sup>31</sup> Overall, widening the opportunities to all types of clinical trials may be one strategic method to improve participation in research for diverse populations.

A limitation of our data, in addition to its retrospective nature, is that all screenings were not represented in our EMR at the time of the study, because screening notes were not uniformly created if there were no open trials for a specific patient. As a result, we have missing information in addition to an underestimated ineligibility if no trial was available. Another limitation is the potential for misclassification of data as some of the reasons for ineligibility had to be categorized retrospectively by chart abstraction, rather than by the person conducting the screening in real time. Finally, other clinical trials are offered at our institution but do not participate in this particular screening mechanism, using the EMR. For example, there was no EMR documentation for eligibility or enrollment for amyloidosis, a disease that is commonly treated at our institution.

Overall, we demonstrate that an EMR cancer trial screening note in the ambulatory care setting provides valuable information to inform accrual patterns and catalyze change within an institution. Having the ability to systematically gather eligibility and enrollment rates from our electronic medical record has helped us to better understand our ambulatory cancer patient population and to identify next steps in improving our accrual onto cancer clinical trials. Recruitment for nontreatment trials may be a future strategy to increase diverse participation and engagement in clinical research. We need to continue to improve understanding and raise awareness of the benefits of clinical trials among our vulnerable patients, while investigating where the true institution-specific barriers lay.

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