Use of the National Cancer Institute Community Cancer Centers Program Screening and Accrual Log to Address Cancer Clinical Trial Accrual

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Abstract

Purpose: Screening logs have the potential to help oncology clinical trial programs at the site level, as well as trial leaders, address enrollment in real time. Such an approach could be especially helpful in improving representation of racial/ethnic minority and other underrepresented populations in clinical trials.

Methods: The National Cancer Institute Community Cancer Centers Program (NCCCP) developed a screening log. Log data collected from March 2009 through May 2012 were analyzed for number of patients screened versus enrolled, including for demographic subgroups; screening methods; and enrollment barriers, including reasons for ineligibility and provider and patient reasons for declining to offer or participate in a trial. User feedback was obtained to better understand perceptions of log utility.

Results: Of 4,483 patients screened, 18.4% enrolled onto NCCCP log trials. Reasons for nonenrollment were ineligibility (51.6%), patient declined (25.8%), physician declined (15.6%), urgent need for treatment (6.6%), and trial suspension (0.4%). Major reasons for patients declining were no desire to participate in trials (43.2%) and preference for standard of care (39%). Major reasons for physicians declining to offer trials were preference for standard of care (53%) and concerns about tolerability (29.3%). Enrollment rates onto log trials did not differ between white and black ($P = .15$) or between Hispanic and non-Hispanic patients ($P = .73$). Other races had lower enrollment rates than whites and blacks. Sites valued the ready access to log data on enrollment barriers, with some sites changing practices to address those barriers.

Conclusion: Use of screening logs to document enrollment barriers at the local level can facilitate development of strategies to enhance clinical trial accrual.

Introduction

Despite a considerable body of literature that focuses on barriers to oncology clinical trial enrollment,¹⁻¹⁰ clinical research sites often lack knowledge about their own, unique enrollment challenges. Tools such as screening logs have the potential to help sites identify barriers and address problems of accrual at the local level, in real time. Screening logs can capture, for specific clinical trials, the number of patients screened for and enrolled onto the trial, the demographics of those patients, reasons for nonenrollment, and methods of screening used, among other data. Prospective, local collection of such data could support tailoring of interventions to promote accrual, which could especially be of help in increasing representation of racial/ethnic minority and underrepresented populations in clinical trials.

Although enrollment barriers have been well documented,¹⁻¹⁰ sites need real-time knowledge of barriers specific to their own site to tailor accrual interventions. The literature provides examples in which data obtained from screening logs were used to

identify strategies to increase accrual.^{11,12} Other tools have been used to screen for trial eligibility, identify gaps in site trial portfolios, and track enrollment.¹³⁻¹⁶ Use and testing of screening or formal screening have been encouraged by the National Cancer Institute (NCI), ASCO, and the American College of Surgeons' Commission on Cancer to address accrual to cancer trials.¹⁷⁻¹⁹ A recent survey of a Cooperative Group, however, indicated that only approximately one third of sites had a formal mechanism for eligibility screening.²⁰

Logs can also be used to identify site barriers that, collectively, slow accrual to a trial or prevent a trial from being completed at all. An NCI review of phase III Cooperative Group trials active between 2000 and 2007 found that an estimated 22% would have insufficient accrual because of an inadequate accrual rate.²¹ At the time of this report, efforts at the national level are underway to promote more timely trial development, activation, and completion.^{22,23} Further, NCI requires the inclusion of recruitment plans in grant applications.

Faced with a need to identify site-specific barriers to enrollment, the NCI Community Cancer Centers Program (NCCCP), a program initiated in 2007 to address cancer health disparities and expand clinical research access at the community level,²⁴ developed the NCCCP Clinical Trial Screening and Accrual Log (the Log). A major objective of the Log is to help participating community sites focus their efforts for enrolling underrepresented populations onto clinical trials, including members of racial/ethnic minorities, elderly patients, and rural patients.²⁵ The Log provides a mechanism for monitoring enrollment of these populations and capturing data to inform the development of strategies to narrow the gap between their enrollment and that of majority populations.

In this article, we present key findings from an analysis of nearly 5,000 Log entries, including enrollment barriers that were identified and enrollment rates of demographic subgroups. To complement these quantitative data, we also gathered feedback from Log users to determine their perceptions of the Log's utility.

Methods

Collecting Enrollment Barrier Data

The NCCCP developed the Log in 2008 as a Web-based tool for collecting de-identified data on patients screened for select trials. After pilot testing by 15 of the 16 original NCCCP sites, a revised version of the Log that included additional barriers was implemented in 2009. In 2010, additional sites joined the NCCCP, increasing participation in the Log to 29 (of 30) NCCCP sites.

Data elements collected in the Log include patient demographics (race/ethnicity, sex, age, rural status, and, if language was a barrier, language spoken); methods used for screening; whether the patient enrolled in the trial; and, if not, provider or patient reasons for nonenrollment or reasons for ineligibility. The Log's full question and answer set is shown in the Data Supplement. Standardized reports can be generated to show real-time accumulation of Log data across these elements, for a single site or across the multiple sites that have entered data.

Trials are selected for placement on the Log by an NCCCP committee, which identifies trials for potential inclusion and determines by vote whether a majority of NCCCP sites are participating in or plan to participate in the trial. All trials are NCI Cooperative Group adult treatment, cancer control, and prevention trials that are available via NCI's Cancer Trials Support Unit. For each trial, NCCCP physician leaders develop a standardized definition of which types of patients are eligible for screening, to prevent inflation of the number screened by inclusion of patients who do not meet basic criteria (eg, the specified pathology or stage of disease) to be considered for the trial. At any one time, typically 10 to 12 trials are included on the Log.

Analysis of Enrollment Barriers

Because Log data were de-identified, the National Institutes of Health Office of Human Subjects Research exempted the analysis from institutional review board review. Log data for 27

trials, from March 2009 through May 2012, were analyzed to assess number of patients screened versus enrolled, including for demographic subgroups and cancer types; methods of screening; reasons for ineligibility; reasons provider declined to offer the trial; and reasons patient declined the trial.

In addition to descriptive statistics, comparisons of enrollment by demographic group and cancer type were performed with χ^2 test or one-way analysis of variance. These were performed with SAS 9.3 software (Cary, NC). A *P* value of less than .05 was considered statistically significant. In the analysis of enrollment rate specifically by race/ethnicity, only patients with complete race and ethnicity data were included. (Rural status was added to the Log later in its use, so was not analyzed in this data set.)

Site Feedback on Log Use

To gain an understanding of users' perceptions about the utility of the Log, we spoke by phone with the 21 current NCCCP sites (ie, those competitively renewed in 2012). The phone conversations were structured to determine how sites used the Log, what they perceived to be its benefits and challenges, and whether sites felt that maintaining a screening log was worthwhile. Notes from the conversations were reviewed for themes.

Results

Patients were screened for at least one of 27 trials open at various times during the data collection period. A list of these trials is provided in the footnotes of Table 1. Most trials were treatment trials (81.5%); the remainder were symptom management trials (11.1%), a prevention trial (3.7%), and a trial with a focus on tissue procurement for molecular profiling (3.7%). By cancer type, the most common trials were breast (25.9%), colorectal (22.2%), and genitourinary (18.5%). Most patients were screened for breast (42.0%), colorectal (26.5%), and lung (8.4%) cancer trials, and for symptom management trials that allowed multiple cancer types (13.9%). Table 1 shows enrollment rates for each cancer type. (Number of screened and enrolled patients per trial is provided in Appendix Figure A1, online only.)

Overall Screened and Enrolled

Data on 4,934 screened patients were entered into the Log. Of these, 451 entries (9.1%) were excluded from the analysis as a result of incomplete or inconsistent data, resulting in 4,483 usable Log entries. A large proportion of patients (42.1%) were ineligible to enroll onto a trial. Of the 2,597 eligible patients, 31.8% were enrolled onto a trial. The overall enrollment rate onto Log trials among those screened was 18.4% (Figure 1).

Screened and Enrolled by Demographic Subgroup

Data on demographics of the patients entered into the Log are shown in Table 1. The median age of screened patients was 62 years (range, 22 to 99). The majority of screened patients were female (67.9%), white (76.1%), and non-Hispanic (83.5%). The oldest old (≥ 85 years) and adolescent/young adults

Table 1. Log Enrollment Rates by Demographics and Cancer Type

Category	No. Screened	% of Screened	No. Enrolled	Enrollment Rate (% of screened who enrolled)	P (difference in enrollment rates)*
All	4,483	100	826	18.4	
Sex					
Female	3,044	67.9	535	17.6	.0328
Male	1,439	32.1	291	20.2	
Age					
18-39	132	2.9	29	22.0	.1100
40-64	2,397	53.5	466	19.4	
≥ 65	1,913	42.7	330	17.3	
Unavailable*	41	0.9	1	2.4	
Race†					
White	3,410	76.1	687	20.2	White, black, other: .0020
Black or African American	532	11.9	93	17.5	White v black: .1512
Other‡	245	5.5	28	11.4	Black v other: .0306
Unavailable*	296	6.6	18	6.1	White v other: .0009
Ethnicity†					
Non-Hispanic/Latino	3744	83.5	767	20.5	Hispanic v non-Hispanic: .7300
Hispanic or Latino	162	3.6	35	21.6	
Unavailable*	577	12.9	24	4.2	
Minority§					
No	3,286	73.3	660	20.1	Minority v nonminority: .0093
Yes	928	20.7	151	16.3	
Unavailable*	269	6.0	15	5.6	
Cancer type					
Breast	1,884	42.0	290	15.4	
Colorectal	1,190	26.5	159	13.4	
Head and neck	54	1.2	8	14.8	
Hematologic	183	4.1	24	13.1	
Lung	378	8.4	71	18.8	
Melanoma	1	0.0	1	100	
Prostate	58	1.3	10	17.2	
Renal	112	2.5	27	24.1	
Multiple	623	13.9	236	37.9	

* Unavailable subgroup was not included in the statistical analysis.

† Race and ethnicity were collected using Office of Management and Budget categories.

‡ Other includes American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, and multiracial.

§ Minority includes non-White race and/or Hispanic ethnicity.

|| Breast trials: CALGB 40603, ECOG E5103, NSABP B-42, NSABP B-43, NSABP B-47, TAILORx, SWOG S1007; colorectal trials: CALGB 80702, CALGB C80405, ECOG E5202, NCCTG N0147, NSABP C-10, NSABP P-5 (prevention); genitourinary trials: CALGB 90601 (urinary tract), ECOG E2804 (renal), ECOG E2805 (renal), RTOG 0831 (prostate, cancer control), SWOG S0421 (prostate); head and neck trial: ECOG 1305; hematologic trials: CALGB 50303 (lymphoma, tissue procurement), SWOG S0777 (myeloma); lung trials: ECOG E1505, ECOG E5508, RTOG 0617; melanoma trial: ECOG 1609; trials of multiple cancers: CALGB 70604, SWOG S0702 (cancer control).

(18-39 years) comprised 3.3% and 2.9% of those screened, respectively.

Enrollment rates onto Log trials were similar among age groups (adolescent/young adults [18-39 years], older adults [40-64 years], and elderly [≥ 65 years], $P = .110$), as well as between white and black racial groups ($P = .151$), and between Hispanic and non-Hispanic ethnic groups ($P = .730$). Patients of other races (American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, and multiracial) had significantly lower enrollment rates than either blacks ($P = .031$) or whites ($P = .0009$).

Methods of Screening Used

The most common methods for identifying patients for screening were chart reviews to verify stage and diagnosis (59.7% of Log records), provider referral (30.8%), clinic schedule review (29.3%), patient navigators (14.8%), multidisciplinary clinics (10.4%), tumor board (9.0%), and pathology reports (7.8%). Less used were registries (3.5%), rounds (0.9%), surgical schedule review (0.9%), patient self-referral (0.1%), pharmacy/chemotherapy lists (this option added later to the Log; 0.1%), and response to advertisement

Figure 1. Reasons for nonenrollment. (A) Reason(s) for ineligibility. (*) A total of 1,973 responses were provided across 1,882 of 1,886 ineligible patients. Four records did not supply reasons for ineligibility. (B) Reason(s) health care provider declined. (†) A total of 614 responses were provided across all 570 providers who declined to offer trial. (C) Reason(s) patient declined. (‡) A total of 1,091 responses were provided across all 944 patients who declined trial participation.

(0.04%). (Note: Log users could select > one method, hence percentages do not sum to 100%.)

Barriers to Enrollment

Reasons for ineligibility. Reasons for ineligibility are shown in Figure 1A. Major reasons were comorbidities (26.6%) and prior treatment (20.9%).

Reasons for nonenrollment besides ineligibility. Of the 1,771 eligible patients who were not enrolled, reasons for nonenrollment included patient declining participation (53.3%), physician declining to offer participation (32.2%), urgent need for treatment (13.6%), and trial suspension (0.9%).

Reasons provider declined to offer the trial. Physicians declined mostly because of preference for the standard of care (53%) or concerns about tolerability as a result of patient comorbidities and frailty (29.3%; see Figure 1B for all reasons).

Reasons patient declined the trial. The major reasons patients declined were lack of desire to participate (43.2%) and preference for standard of care (39%; see Figure 1C for all reasons).

Log Use at the Site Level

Sites found tracking screening and accrual data to be beneficial, with most (20 of 21) expanding their collection of such data to encompass all oncology trials (NCI and non-NCI trials) at their site, beyond those included in the NCCCP Log.

Benefits perceived included the Log's role in helping sites to assess their performance in accruing to individual trials, manage their trial portfolio, identify enrollment barriers, understand their site's demographics, and assess staff performance in patient recruitment. Having a trial included on the Log heightened clinician awareness of the trial at the site, as screening data could be adduced to demonstrate level of effort in screening for the trial. Such documentation was felt to be especially important for trials that accrued poorly despite best efforts. Moreover, sites felt that the Log aided them in providing accurate data reports to cancer committees, multidisciplinary conferences, and accrediting bodies (eg, Commission on Cancer), as well as in demonstrating to potential industry sponsors the site's capacity to conduct trials.

Challenges to Log use included lack of staffing or time to gather and enter the data, numerous response options to read

through for reasons for nonenrollment, too many unique log forms required by different trial sponsors, competing priorities, and geographic and/or organizational separation of clinical from research staff. Competing priorities included patient care needs, implementation of a new electronic health record system, and more pressing trial-related activities such as addressing toxicities and study monitor visits. Separation of clinical from research staff could make it difficult for staff to ascertain why a clinician did not enroll patients onto a trial, which necessitated looking through progress notes, waiting to ask the provider, or engaging in several back-and-forth communications for clarification. With regard to addressing these difficulties, sites emphasized the importance of incorporating Log use into the site's workflow.

Discussion

Our collection of Log data from nearly 5,000 patients from 29 community cancer centers across 22 states shows that implementation of a uniform tool to track barriers to trial accrual is feasible on a national scale. Moreover, this collection took place during a time (2009-2012) of major changes in the NCI clinical trials enterprise, economic uncertainty, and health care reform.

Potential utility of this type of log data is broad. In addition to providing accrual and barrier data to individual institutions, aggregated Log data could be provided as feedback to study chairs. Trials with challenging accrual were discussed on monthly teleconferences, some of which were attended by study chairs who presented to the NCCCP and discussed accrual strategies. As one example, NCCCP input contributed to changes in eligibility criteria and the development of an educational tool for NSABP-P-5, a colon cancer prevention trial. On the calls, sites could also compare barriers they were experiencing to determine whether they were trial or site related. High-accruing sites shared how they approached a patient for a trial, advertised for a trial, and addressed problematic eligibility criteria.

During our conversations with Log users, many stated that, despite challenges, they valued the ready access to data on screening, accrual, and enrollment barriers afforded by the Log. Those sites that incorporated the Log into their normal workflow, with staff aware of how it figured into the daily functioning of their site, appeared to have an easier time with implementation.

Some sites described changes brought about at their site in direct response to data captured by the Log. For example, when Log data revealed a loss of potential clinical trial participants at one site as a result of urgency to treat aggressive disease, the site adjusted its chart review process to alert physicians of patients' potential eligibility earlier on. Another site used Log data to determine whether or not translating its informed consent forms into certain languages was justified. When Log data for one site showed that missed surgical biopsies were rendering patients ineligible for a trial, the site set in place systems to alert the surgeons and research staff when a patient was a candidate for such a biopsy. Subsequently, the site became a high accruer nationally for the trial. Finally, when Log data pointed to a need

for patient travel support and copayments for supportive drugs, sites sought these supplemental resources.

Logs can also provide metrics for staff performance and document level of effort involved in screening. Indeed, sites especially appreciated how the Log data made manifest the site's significant screening efforts, which were otherwise not always apparent to other staff. As targeted therapies are increasingly studied in the treatment of cancer, requiring more intensive screening of potential trial participants, screening logs such as that used by the NCCCP may in the future become especially helpful in tracking screening efforts vis à vis ineligibility.

Improvements in trial efficiency and timeliness of trial completion are a major focus of the NCI's response to the Institute of Medicine recommendations to reinvigorate the national clinical trials enterprise.²³ This response has included implementing the Operational Efficiency Working Group recommendations²² and building the forthcoming NCI National Clinical Trials Network.²⁶ By providing real-time information on accrual rates and enrollment barriers, particularly for slowly accruing trials or trials with more patients declining participation than expected, screening logs can help identify enrollment difficulties more quickly. Further, this information can help sites refine their trials menu, closing trials when barriers are too great.

Moreover, the Log has shown that within NCCCP institutions, disparity in trial accrual may have narrowed among certain demographic subgroups. Specifically, we did not see a statistical difference in enrollment rates into Log trials between elderly and the young, Hispanic and non-Hispanic, or between white and black races. This compares favorably against a cross-sectional, population-based study that showed 65% and 30% lower accrual rates among elderly and black patients, respectively, in Cooperative Group treatment trials in major cancers during 2000 to 2002, and a continuous decline in the proportion of black trial participants from 1996 to 2002.²⁷ The accrual for nonblack racial minority groups remains a challenge, however, as they were nearly 50% less likely to participate in a trial compared with whites (Table 1).

We show that ineligibility, at 42% of screened patients, was the most common barrier to accrual among the trials selected for the Log. This rate seems to be higher than previous reports in both academic (16%) and community (24%) settings.^{6,8} Although comorbidities, frailty, and prior therapy remained important reasons for ineligibility, stricter eligibility associated with biomarker criteria or additional pathology submission requirements may be emerging barriers not as frequently seen in the past. These barriers are likely to increase as new trials increasingly target specific molecular subtypes and incorporate more correlative studies. Likewise, logs can help capture trial refusals in trials for which patients learn their potential risk level via molecular subtyping and then are randomly assigned to more versus less aggressive treatment (eg, chemotherapy *v* no chemotherapy).

Our results suggest that there are ample opportunities to enhance trial awareness, as more than half of the reasons for patient and physician declining a trial were related to lack of

desire to participate or preference for standard of care (Figures 1B and 1C). Almost 30% of physicians who declined to offer a trial cited patient comorbidities or frailties that were not part of eligibility criteria. This could imply that community physicians are generally more conservative than what trials allow and that patients who do enroll onto clinical trials are healthier than what the eligibility criteria suggest. Compared with recent studies, socioeconomic barriers seem to be more frequent, and drug unavailability emerged as a new barrier (Figure 1B).^{6,8} Chemotherapy drug shortage has indeed escalated in the past year and may adversely affect treatment outcome even when a substitute drug is used.^{28,29}

Limitations of our analysis include variation over time in the number of trials included on the Log, in number of Log trials open by an individual site, and in number of sites participating in the Log (ie, timing of sites' initiation of Log use). Only select trials were tracked on the Log. Almost 10% of records had incomplete or inconsistent data, and race and ethnicity were unavailable for 6.6% and 12.9% of patients, respectively. Not all 30 NCCCP sites were interviewed, but rather only the sites that renewed in 2012. Perhaps noncontinuing sites would have had other impressions, positive or negative, about the Log's utility. Lastly, we did not systematically evaluate whether interventions that resulted from Log use led to increased accrual or infrastructural and/or practice changes intended to increase accrual. Such information would be important to track in the future.

In conclusion, a screening and accrual log can be a valuable tool for clinical research sites to gain an understanding of their enrollment barriers in order to develop tailored strategies to address them. Such tracking can especially address enrollment of historically underrepresented populations. Logs can also provide trial-specific data to trial leaders to elucidate reasons for low accrual. To maximize a log's utility, the log should be integrated into the workflow of a site.

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Appendix

Figure A1. Patients screened and enrolled, by clinical trial, in the National Cancer Institute Community Cancer Centers Program Clinical Trial Screening and Accrual Log, March 2009-May 2012. H&N, head and neck.