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Discussions of Cancer Clinical Trials with the National Cancer Institute's Cancer Information Service

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Abstract

Clinical trials are essential for the development of new and effective treatments for cancer; however, participation rates are low. One reason for this is lack of knowledge about clinical trials. This study assessed how often clinical trials are discussed on calls to National Cancer Institute's Cancer Information Service (CIS). The authors quantitatively analyzed 283,094 calls to the CIS (1-800-4-CANCER) over 3 years (2006–2008). They calculated descriptive statistics and multivariate regressions to determine whether specific caller characteristics are associated with the presence of a clinical trials discussion. In addition, 2 focus groups were conducted with CIS information specialists (n = 12) to provide insight into the findings. The authors found that approximately 9.3% of CIS calls discussed clinical trials, with higher percentages for patients (12.5%) and family members (15.4%). Calls with Hispanics, Blacks, and Spanish speakers were less likely to include a conversation. For all cancers, patients who are in treatment or experiencing a recurrence were statistically significantly more likely to discuss clinical trials. CIS information specialists reported callers' limited knowledge of clinical trials. The CIS has the unique ability to make a substantial effect in educating patients about clinical trials as an option in cancer treatment and care.

Cancer clinical trials are essential for the development of new and effective treatments for cancer. For trials to produce valid and generalizable results, effective accrual of participants is necessary. Unfortunately, rates of participation in adult cancer clinical trials are low. A national study of recruitment to National Cancer Institute (NCI)–-sponsored trials estimates the overall recruitment rate to be less than 2% of all newly diagnosed cancer patients

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(Murthy, Krumholz, & Gross, 2004). At individual cancer centers, recruitment of newly diagnosed patients is higher, but still minimal, approximately 5–14% (Benson et al., 1991; Lara et al. 2001; Sateren et al., 2002; Spiro, Gower, Evans, Facchini, & Rudd, 2000). An additional concern is the underrepresentation of minorities in cancer clinical trials. With the exception of prostate cancer, national population-based studies have shown that Blacks and Hispanics participate in clinical trials at much lower rates than would be expected from cancer incidence rates in these populations (Gross, Filardo, Mayne, & Krumholz, 2005; Murthy et al., 2004; Simon, Brown, Du, LoRusso, & Kellogg, 1999). This underrepresentation of minorities is not improving; to the contrary, participation by Blacks and Hispanics had fallen over time, even though overall recruitment had risen (Murthy et al., 2004).

There is a growing body of research examining the question of why overall recruitment rates remain low and why ethnic and socioeconomic disparities exist. Prospective surveys of physicians treating newly diagnosed cancer patients have found only one third to two thirds of all cancer patients are even considered by the physician for participation in research (Fleming, 1994; Simon et al., 1999). Physicians reported they did not consider or offer participation when they believed appropriate protocols were unavailable, when they believed the patient would be ineligible for available protocols, or when the patient was in poor health (Fleming, 1994; Siminoff et al., 2000). In addition, studies show participation is systematically less likely to be offered to older individuals and minorities (Siminoff, Zhang, Colabianchi, Sturm, & Shen, 2000; Simon et al., 2004) even though these individuals may be willing to participate if offered enrollment. One study noted that lack of resources and time for recruitment are often cited as major barriers to trial accrual (Ellis, Butow, Simes, Tattersall, & Dunn, 1999), and these constraints may well be more severe among physicians treating minorities and the elderly.

Recent research has also looked at reasons why cancer patients choose not to participate in clinical trials. Some patient-provided reasons include reluctance to be in a study, financial and time constraints, and lack of understanding of trials (Brown, Fouad, Basen-Engquist, & Tortolero-Luna, 2000; Fleming, 1994; Fouad et al., 2001; Schain, 1994). However, one of the most pervasive barriers to participation in cancer clinical trials is lack of awareness and knowledge about trials (Advani et al., 2003; Du, Mood, Gadgeel, & Simon, 2008, 2009; van Stujvenber et al., 1998). For example, Taylor and Leitman (2001) found that up to 85% of cancer patients are unaware that clinical trials are a treatment option. Patients who decline or are uncertain about participation are likely to cite “need more information” as a reason (Sutherland, da Cunha, Lockwood, & Till, 1998). In addition, patients have many misconceptions about trials, including beliefs that they may receive a placebo and not understanding randomization (Du et al., 2009). Therefore, improving knowledge and awareness of clinical trials is important and may lead to improved participation rates in cancer treatment trials.

Patients can obtain information about cancer clinical trials from a number of different sources, including their own physician, a research nurse or physician, and the Internet. A recent growing body of literature has explored communication between the patient and his or her physician, and information seeking on the part of the patient, in relation to clinical

trials. Although communication is generally viewed as important to overcome barriers to recruitment (Ridda, MacIntyre, Lindley, & Tan, 2010; Yang et al., 2010a), one study found that individuals may be afraid to ask for information even from a trusted doctor (Udrea et al., 2009). Other studies have identified factors that were positively associated with willingness to discuss and information seeking about clinical trials. These factors include perceived fairness of the interaction by the patient, trust in the doctor, and optimism (McComas et al., 2010; Yang et al., 2010b).

Information that patients report they need concerning clinical trials include understanding foundational information about trials, information on conflict of interest issues, and personal monetary costs of joining a study (Brown et al., 2011a). Research has also looked at what means of getting information is most preferred and most effective. Studies on understanding of informed consent have shown that a computer-based provision of information was preferred to a paper format (Karunaratne, Korenman, Thomas, Myles, & Komesaroff, 2010), and that videos explaining informed consent not only improve understanding but also made individuals more comfortable to ask questions of the physician (Hazen et al., 2010). In addition, the use of a question prompt list has been proposed as a means of improving communication and transfer of information between physicians and patients (Brown et al., 2011a, 2011b).

Although much of the previous literature has focused on physician–patient communication or multimedia instruments as the means by which patients receive information on clinical trials, it is generally agreed that education by any means is needed to raise awareness, reduce fears and dispel myths about clinical trials participation (Jones et al., 2006).

One important source of information on clinical trials, that has not been previously studied, is the NCI's Cancer Information Service (CIS). The NCI's CIS is an information and health communication program designed to meet the cancer information needs of the public, especially cancer patients and their families (Squiers et al., 2006). The CIS provides information on all aspects of cancer for patients, their families, and the general public through an English/Spanish telephone service (1-800-4-CANCER), LiveHelp instant messaging (English only), and e-mail (English and Spanish). Highly trained CIS information specialists have access to comprehensive cancer information and provide thorough and individualized responses to questions across the cancer continuum, including prevention, early detection, diagnosis, treatment, and end-of-life care. In addition, CIS information specialists are trained and prepared to proactively discuss clinical trials with clients, providing personalized clinical trials searches and translating complex scientific information into understandable terms. Consistent with current research (Brown et al., 2011a, 2011b), the CIS information specialists use question prompt lists during discussions of clinical trials. Given that the CIS receives a large volume of calls through its telephone service (N = 283,094 from 2006 to 2008), this resource has the potential to educate a large population on clinical trials. The focus of this article is on cancer treatment trials given the large percentage of clinical trial calls (97.3%) that focus on treatment trials compared with prevention/screening trials (2.7%).

This research is a novel assessment of how frequently calls to the CIS involve discussions of treatment-related clinical trials and of the characteristics of callers and calls where such discussions take place. The specific guiding research questions for this study are as follows:

1. Overall, how commonly are clinical trials discussed outside a physician-patient setting such as on the CIS telephone service?
2. Are there significant and substantial differences in prevalence of discussions on the basis of race, ethnicity, or the language in which the call was made?
3. Does the stage of a patient's cancer significantly and substantially affect rates of discussions?
4. What is the nature of clinical trials discussions (e.g., caller attitudes toward and interest in clinical trials, who initiates the discussion)?

Method

To answer the guiding research questions of this study, we conducted an analysis of 3 years of CIS call data and two focus groups with CIS information specialists who routinely engage with CIS callers on the topic of cancer clinical trials.

In particular, we obtained data for this study from national call data collected using a web-based Electronic Contact Record Form (ECRF) at the three CIS contact centers (in Miami, Florida; New York City, New York; and Seattle, Washington) that existed at the time of data collection. The focus groups with information specialists were conducted at the Coastal CIS Contact Center located in Miami, Florida. This Contact Center handled regional English language calls and all Spanish language calls. The CIS program now operates out of the Fred Hutchinson Cancer Center in Seattle as a single NCI contact center.

In 2009, the lead author from the University of Miami Sylvester Comprehensive Cancer Center partnered with key CIS staff from the University of Miami (Coastal CIS) and the University of Kentucky (Mid-South CIS) to analyze national call data and to conduct the focus groups. The CIS staff, as contractors of the NCI, had access to national ECRF records, which were used for the quantitative analyses. In addition, CIS staff facilitated recruitment of information specialists at the Coastal Contact Center for the focus groups.

Quantitative Data Source and Collection

As part of usual service, the CIS collects detailed, standardized information about client interactions via the web-based ECRF. On the basis of information that emerges during the course of the telephone conversation, CIS c code type of user (e.g., patient, friend/family member, general public), type of cancer discussed, stage in the cancer care continuum if the caller is a patient (e.g., in treatment, posttreatment, recurrence) and subject of interaction reflecting the questions asked and topics initiated by the caller or information specialist (e.g., clinical trials, referral to medical services, treatment/side effect management). All variables have precoded response options; up to three sites can be coded for cancer site discussed and up to five subject of interaction codes may be entered for a single call. In addition, the CIS has approval from the Federal Office of Management and Budget

(approval 0925-0208) to proactively collect from every caller how they heard about the CIS, if they have contacted the CIS before and their zip code. For this study, ECRF records were used for all calls received through the CIS toll-free number from 2006 to 2008. Calls were flagged as including a discussion of clinical trial if coded with the Subject of Interaction code ("Cancer Clinical Treatment Trials") or the Response to Caller code ("Clinical Trials") in the ECRF.

The Office of Management Board approval also allows for the proactive collection of sociodemographic information (e.g., age, sex, ethnicity/race, education, income, health insurance) on a random sample of up to 25% of all contacts on all CIS access channels. During this study time, demographic information was collected for 19% of telephone contacts.

All information specialists are trained in ECRF data collection and coding procedures. CIS ECRF data are managed centrally by the CIS national program (Bethesda, Maryland). Validity and logic checks are incorporated into the ECRF to ensure accurate and complete coding. Validity checks ensure all fields are completed before a record can be saved, and the proper format is used when entering a code. Logic checks ensure that the proper combination of codes is used when completing and saving a record.

Quantitative Data Analysis

We first calculated descriptive frequencies for all callers to the CIS and the percentage of calls that included a discussion of clinical trials. We calculated this value by type of cancer, identity of callers, language of call, and all demographic variables.

We used multivariate logistic regressions to identify which characteristics of calls/callers were statistically significant and associated with the likelihood of a clinical trials discussion. For these analyses, we included only those calls where demographic information had been collected. We ran regressions for all callers, and then separately for patients and family members/friends. Last, we ran similar regressions separately for the five most common cancer types (breast, prostate, colorectal, lung, and other gastrointestinal), including only calls by cancer patients.

Qualitative Data Source and Collection

We conducted focus groups to collect qualitative data as a way to gain a deeper understanding of the needs and concerns of callers inquiring about cancer clinical trials. The aim of the focus groups was to gain insight into the nature of the discussions about clinical trials; for example, is it most commonly the information specialist or the caller who initiates a discussion of clinical trials? The information specialists were recruited by the first author via an e-mail invitation that was distributed to all CIS information specialists employed at the CIS Coastal region at that time (n = 22). Participation was voluntary and no compensation was provided. Two 1.5-hr focus groups were then conducted during March 2009, each with six bilingual information specialists (n = 12). Bilingual information specialists were specifically sought so that the content of conversations with English- and Spanish-speaking callers were included in the focus group discussions.

Each focus group was led by an experienced moderator who guided the staff through a series of open-ended questions that were developed on the basis of preliminary findings from a review of the literature and the quantitative ECRF data. Information specialists were asked to specifically recall phone conversations that centered on cancer treatment clinical trials, describing scenarios in which the discussion of trials evolved. Focus group questions were followed by probes that attempted to gain additional information on the following: frequency and duration of clinical trials calls, who initiated the trials conversations, characteristics of the caller (i.e., anxious, desperate, well-informed, younger, family member, cancer patient), differences between Spanish- and English-language calls, caller attitudes toward and interest in clinical trials, additional caller questions and concerns, and common myths and misconceptions regarding clinical trials. The focus groups were audiorecorded, transcribed, and analyzed for descriptive information related to information specialists' experiences in providing callers with cancer clinical trials information. Qualitative data analysis software was not used; however, all authors of this study read the transcripts multiple times to immerse themselves in the discussion content. Summative results were refined through an iterative process of reading and rereading transcripts, debating, and resolving themes; justifying differing viewpoints; and further examining narratives that departed from initial findings (Schoenberg, Hatcher, & Dignan, 2008).

Results

Throughout this section, all results noted as significant are statistically significant. For the 3 years of data analyzed, there were 283,094 total calls to the CIS and 53,645 (19%) of these calls were sampled for demographic data (see Table 1). Among all callers, 163,563 (57.7%) were patients and/or a family member/friend of a patient. Breast cancer was the most common site discussed (28.3% of calls). Slightly more than 5% calls were conducted in Spanish. In contrast with English-language calls, the majority (57%) of Spanish-language callers were members of the general public.

Sociodemographic Characteristics

Of the calls sampled for demographics, three quarters were female (75.9%) and the majority were White (78.6%). Approximately one third of the callers had a high school education or less, and more than half of the callers were 50 years of age or older. Callers who were family members/friends tended to be younger than patient callers. Approximately one third (36.6%) reported an annual household income of less than $30,000. The majority (80.4%) reported having insurance coverage.

Clinical Trial Discussions

Overall, approximately 9.3% of CIS calls discussed cancer clinical trials with the frequency of discussions of clinical trials slightly higher among diagnosed patients (12.5%) and family members/friends (15.4%). Table 2 shows the percentage of calls that discussed trials, differentiated by cancer type and demographics. It is interesting that only 5.2% of calls concerning breast cancer included a discussion of clinical trials, whereas calls that focused on melanoma, colorectal cancer, and lung cancer had much higher rates of clinical trials discussions (28.5%, 16.2%, and 15.8%, respectively). Calls with women were less likely to

include a clinical trials discussion (9.8% female vs. 14.5% male). Calls with Hispanics and Blacks, and Spanish language calls were less likely to involve a clinical trials conversation. Clinical trials callers were skewed toward callers with more education and higher household income. Last, the number of calls that included a conversation about cancer treatment clinical trials dropped from 10,894 in 2006 to 7,058 in 2008, mirroring the trend in overall CIS call volume, which declined from 103,544 contacts in 2006 to 87,301 in 2008. Overall volume to other CIS access channels, namely e-mail and LiveHelp instant messaging, increased by 44.2% from 2006 to 2008.

Additional analysis revealed that for all calls that included a discussion of clinical trials, 41.2% included a customized clinical trials search conducted via www.cancer.gov or www.clinicaltrials.gov. Calls that included a clinical trials conversation were statistically significantly longer than those which did not include such a discussion ($p < .0001$); this held true for English- and Spanish-language calls. As an example, 58.2% of calls that did not include a discussion of clinical trials were 15 minutes or less in length compared with 32.3% of calls that did include a discussion, thus an effect size of .25.

Table 3 presents results from the multivariate logistic regressions of all callers, patients, and family members to determine what factors are significantly associated with clinical trials discussion. Income and insurance coverage were not included, as there is a high rate of missing values for these variables as a result of user refusal, user breakoff, or other reasons. Controlling for all other variables, clinical trials discussions varied by cancer type and by racial/ethnic groups.. For example, calls focusing on breast cancer were significantly less likely to include a clinical trials discussion as compared with prostate cancer (OR = 0.66; 95% CI [0.59, 0.75]), whereas calls about melanoma were significantly more likely to include a discussion (OR = 2.59; 95% CI [2.20, 3.04]). Black and Hispanic callers were significantly less likely to discuss clinical trials (ORs = 0.62 and 0.70, respectively). Spanish language calls were significantly and substantially less likely to include a clinical trials discussion (OR = 0.58; 95% CI [0.40, 0.83]). There was a strong relation between education and likelihood of a clinical trials conversation. The frequency of clinical trials discussions decreased significantly over time. However, over this time period there was also an increase in the use of the LiveHelp online chat service and an increase in the number of interactions that involved discussions of clinical trials (462 in 2006 to 990 in 2008).

To determine whether the stage of treatment was associated with presence of a clinical trials discussion and whether the disparities found above are consistent across cancer types, we conducted multivariate regressions by cancer type (see Table 4). There were fewer significant findings in these regressions, possibly because of smaller sample sizes. Disparities in rates of clinical trials discussions were not consistent across cancer type. However, for all cancers, patients who are in treatment or experiencing a recurrence were significantly more likely to discuss clinical trials than a newly diagnosed patient.

Focus Groups

The focus groups provided insight into the nature of the clinical trials discussions. A notable finding was the difference between the information specialists' perceptions of how many of their calls involve a discussion of clinical trials as opposed to the number of calls where

clinical trials was actually coded. The quantitative data showed that only 9.3% of calls involve clinical trials conversations, whereas the information specialists perceived that anywhere between 30% and 70% of their calls included clinical trials discussions, depending on the language of the call, with Spanish calls less likely to involve clinical trials conversations. This overall dissonance may be attributed to information specialists spending significantly more time on calls that involve clinical trials discussions, explaining the intricacies of clinical trials including phases, randomization, eligibility criteria, and human subject protections. Therefore, information specialists may perceive they are talking about clinical trials on many of their calls because the calls that do discuss clinical trials are time consuming and detailed. In addition, given the length and complexity of these calls, it is possible that clinical trials discussions are under coded.

Another topic that was raised in the focus groups was the difference between clinical trials discussions initiated by the caller and those initiated by information specialists. Conversations about clinical trials are most often initiated by the information specialists, primarily when clinical trials are included as treatment options in NCI's Physician Data Query Treatment Summaries. The information specialists introduce clinical trials as a viable treatment option and assess the callers' interest in continuing the clinical trials discussion or proceeding with other conversation topics.

When clinical trials conversations are initiated by the caller, the discussions can be placed in two primary categories: (a) callers who are focused on a specific request that might have been prompted by their own online research, a story in the media, or a recommendation by another cancer patient; and (b) callers who are "grasping for hope" or "searching for a needle in a haystack" after the physician has told the family there are no remaining treatment options. The callers in the latter group are adamant in their need to get themselves or a loved one enrolled into a study that may provide a "miracle cure," whereas the former callers may ask about specific drugs that are being tested in trials. The majority of callers require substantial education about the clinical trials process as a result of the misconceptions and myths concerning trials. Information specialists noted callers often have a misunderstanding of the types of trials (i.e., prevention, screening, diagnostic, treatment, supportive care); applicability of certain trials and treatments for their specific type of cancer; the randomization process; the use of placebos in treatment trials; the sequential phases of clinical trials and drug development; human subjects protection; inclusion and exclusion criteria; physician-to-physician referral processes; and costs associated with clinical trials participation. The information specialists anecdotally noted callers' fear of being treated like a "guinea pig" or a "rat in a laboratory."

Consistent with the quantitative data analysis, focus group participants indicated that Spanish-speaking callers are less likely to talk about clinical trials. This may be because Spanish-speaking callers are significantly more likely than are English-speaking callers (57.0% vs. 27.6%) to be members of the general public (not diagnosed cancer patient or related to cancer patient). Therefore, the subject of the CIS interaction is more often focused on prevention and screening, and connecting callers to community-based resources for these services. CIS staff commented that for Spanish-language callers who are primarily focused

on financial assistance and/or screening services, engaging in a clinical trials conversation may be inappropriate.

Last, on the basis of information specialists' conversations with callers, physicians are often seen as indifferent or unhelpful regarding clinical trials participation. Callers reported that their physician placed the responsibility for finding information about clinical trials on them; in essence, having "patients do their own homework." In some instances, the physician recommended that the patient call the CIS for information on trials.

Discussion

This study reports on the results of quantitative and qualitative analyses conducted to better understand CIS client interactions where treatment-related clinical trials were discussed. The information collected was used to answer the specific questions guiding the research. Here we summarize the highlights.

- Overall, how commonly are clinical trials discussed outside a physician–patient setting such as the CIS telephone service?

  Over the 3-year period from 2006 to 2008, the percentages of cancer patients and family members/friends who discussed clinical trials were 12.5% and 15.4%, respectively. The rate for all callers was 9.3%. Therefore, clinical trials were not discussed in the majority of CIS calls.

- Are there significant and substantial differences in prevalence of discussions on the basis of race, ethnicity, or the language in which the call was made?

  There were substantial disparities by race, ethnicity, and language of the call. Compared with Whites, Blacks had a 40% less chance of having a discussion of clinical trials as compared with Whites, and Hispanics had a 30% less chance. Spanish-language calls were substantially (OR = 0.58) less likely to include a discussion of clinical trials, possibly because of several factors including the fact that the majority of Spanish callers to the CIS are members of the general public. These callers are more likely concerned with early detection and financial assistance for such services and not as likely to be considering treatment-oriented research studies.

- Does the stage of cancer significantly and substantially affect rates of discussion?

  Across all cancer types, we found that patients in treatment and patients with a recurrence of their cancer are significantly more likely to have a discussion about clinical trials. This is a particularly large effect for recurrent cancer. Information from the focus groups support this as information specialists reported that individuals and families for whom standard treatment has failed are particularly anxious for information on clinical trial, and are "looking for a miracle."

- What is the nature of clinical trials discussions?

  The length and nature of the CIS clinical trials discussions indicate the complexity of clinical trials information and the needs of callers to have more in-depth

conversations with information specialists on this important topic. Information specialists readily acknowledged few callers initiate a conversation about clinical trials; therefore, CIS staff have the opportunity to introduce trials as a treatment option when appropriate. However, as revealed in the focus group discussions, the overall uncertainties and misconceptions callers have about clinical trials may explain the longer duration of these interactions. Information specialists noted "some people have the perception that a clinical trial is either going to cure them or kill them." In addressing this spectrum of beliefs, staff must start with the "fundamentals of clinical trials." In providing factual information about clinical trials in an understandable and tailored manner, information specialists are able to allay fears and concerns regarding the clinical trial process and promote the patient–provider relationship in considering trials as a potential treatment option. Ideally, clinical trials search results are meant to be shared with the caller's physician to aid in the decision making process. As one information specialist noted, "we are not trying to convince, only educate."

Future of Clinical Trials Education

Our findings of disparities in clinical trials discussions with the CIS are consistent with data from clinical trials participation research (Ford et al., 2008; Sateren et al., 2002). Increasing minority representation in clinical trials is a priority for the National Institutes of Health. Without adequate representation of all racial/ethnic groups, the results from randomized clinical trials cannot be generalized to these groups, and thus, the quality of care for racial/ethnic minority patients may suffer (Emanuel, Wendler, & Grady, 2000; Swanson & Bailar, 2002).

In a recent review of the literature from 1996 to 2005, "awareness barriers" was identified as one of the three categories of barriers to recruitment of underrepresented populations into cancer clinical trials (the others are "opportunity" and "acceptance" barriers). Quantitatively, studies have documented an association between lack of awareness of trials and reduced participation (Advani et al., 2003; Lara et al. 2005; Trauth et al., 2005). Qualitatively, lack of education regarding clinical trials, lack of culturally appropriate information, and low cancer knowledge were all patient barriers to participation. The CIS and other nontraditional physician/patient settings have the potential to play an important role in improving the dissemination of information about clinical trials and raising awareness of clinical trials as a treatment option for all callers, including racial/ethnic minorities and particularly non-English speakers.

While our qualitative and quantitative analyses are informative, additional areas for future research include identifying effective ways to provide clinical trials information outside the traditional physician/patient interaction and determining the effect of such education/information on actual clinical trials participation. This could occur within the CIS and in other settings. Furthermore, as we found in the CIS data, an increase in e-mail and LiveHelp contacts is occurring over time. It will be important to determine the differential effect of communicating about clinical trials via these different methods. Online provision of information could include use of an interactive website or video. This might be a more

informative method for providing information, especially as patients and family members could view the information or video more than once.

Limitations

This study has several limitations. Data were analyzed for callers who contacted NCI's CIS. Generalization from this population is limited given that those who contact the CIS can be classified as active information seekers and may represent those with higher motivation and interest in cancer-related issues. It is difficult to determine whether these callers are representative of the general population of cancer patients and their family members. Therefore, caution should be exercised in generalizing to other populations.

Data for this review were collected as part of regular service provision in the CIS program rather than as part of a research protocol. As such, the data is subject to the limitations that occur for passively collected data collected in the context of regular service delivery. While information specialists are trained to complete data collection immediately after each call, it is possible that some aspects of the call may be under-reported and thus underestimated. Given that clinical trials calls tend to be complex and long, some aspects of those calls may be under coded.

Last, we note that the presence of a discussion about clinical trials does not necessarily lead to improved participation rates in treatment studies; and callers report many barriers to participation. Nevertheless, these types of discussions contribute to improved awareness of cancer clinical trials.

Conclusions

While health care provider encouragement is critical to enrollment in cancer treatment trials, raising cancer patients' and family members/friends' knowledge and awareness of clinical trials as a treatment option has the potential to increase shared decision making related to participation. A 2000 report from the Summit Series on Clinical Trials indicated 80% of surveyed cancer patients did not consider clinical trials because they were simply unaware of trials as a treatment option for their cancer (Comis et al., 2000). As the voice of the National Cancer Institute, the CIS has the unique ability to make a substantial effect on increasing patient knowledge and awareness of treatment-oriented trials. Through access to NCI resources, inclusion of oncology certified nurses as CIS staff members, and focused clinical trials training and support to frontline information specialists, the CIS is poised to continue educating callers about the importance of clinical trials as an option in cancer treatment and care. Knowledge gained in the provision of clinical trial information in the CIS setting could also inform other providers of clinical trial information as to the potential of effectively educating a broader audience and the implications for increasing overall participation in cancer clinical trials.

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Table 1

Demographics of callers to the National Cancer Institute's Cancer Information Service

	All callers (%)	Patients (%)	Family (%)
Identity of caller (*n* = 283,094)			
Patient	25.7		
Family member	32.1		
Other	42.2		
Cancer type (*n* = 217,209)			
Prostate and other urogenital	12.7	15.9	12.7
Breast	28.3	30.0	14.2
Colorectal and other gastrointestinal	15.3	12.5	20.3
Hematologic	7.2	7.8	9.4
Skin	3.8	4.2	3.5
Gynecologic	9.1	8.8	7.1
Lung and other respiratory	9.4	7.8	13.8
Head and neck	3.7	3.1	4.8
Melanoma	2.5	2.7	3.1
Other	8.1	7.2	11.2
Language of call (*n* = 283,075)			
Spanish	5.5	3.1	4.2
English	94.5	96.9	95.8
Gender (*n* = 53,645)			
Female	76.0	68.8	79.5
Male	24.1	31.2	20.5
Race (*n* = 47,584)			
White	78.6	79.5	79.6
Black	14.6	14.9	13.2
Other	6.8	5.6	7.2
Ethnicity (*n* = 52,240)			
Hispanic	12.9	7.90	10.8
Non-Hispanic	87.1	92.1	89.3
Age, in years (*n* = 52,872)			
40 and younger	22.1	8.9	24.7
41–50	21.8	17.7	23.8
51–60	23.2	25.2	23.1
61–70	18.5	25.8	17.1
71–80	11.0	17.1	9.2
81 and older	3.4	5.4	2.2
Education (*n* = 52,348)			
Less than high school	9.1	9.5	6.6
High school graduate	25.8	25.8	24.4
Some college	29.3	30.0	28.7

	All callers (%)	Patients (%)	Family (%)
College graduate	23.1	21.2	25.8
Postgraduate schooling	12.8	13.5	14.4
Annual household income (*n* = 22,532)			
Less than $20,000	16.4	18.0	11.6
$20,000–$29,000	20.3	21.3	16.0
$30,000–$39,000	17.9	17.3	17.3
$40,000–$59,000	14.5	14.6	15.6
$60,000–$79,000	18.6	17.8	22.9
$80,000 and greater	12.3	11.1	16.6
Insurance (*n* = 33,309)			
Any coverage	80.4	89.5	84.8
Year			
2006	36.6	34.6	35.6
2007	32.6	31.9	31.7
2008	30.8	33.5	32.7
Discussion of clinical treatment trials (*n* = 283,083)			
Yes	9.3	12.5	15.4

Note. The number of callers for each variable represented the “all callers” category. The sample sizes vary as demographic information is collected from a subset of all callers. In addition, sample sizes vary somewhat for each variable as a result of differences in refusal rates, disconnects, and other factors.

Table 2

Percentages of calls that included a discussion of clinical treatment trials

	All callers (%)	Patients (%)	Family (%)
Cancer type			
Prostate and other urogenital	11.8	13.8	13.6
Breast	5.2	7.7	9.4
Colorectal and other gastrointestinal	16.3	17.4	20.5
Hematologic	12.0	12.8	12.6
Skin	8.2	8.7	10.9
Gynecologic	10.3	14.9	15.7
Lung and other respiratory	15.9	17.5	17.7
Head and neck	11.2	12.2	14.7
Melanoma	28.5	28.4	32.9
Other	18.4	17.3	22.3
Language of call			
English	9.7	12.8	15.7
Spanish	3.1	4.2	8.1
Gender			
Male	14.5	17.9	20.7
Female	9.8	11.9	15.3
Race			
White	12.5	15.1	18.0
Black	7.0	9.0	10.7
Other	10.4	12.0	16.3
Ethnicity			
Non-Hispanic	11.9	14.3	17.3
Hispanic	4.9	7.5	10.2
Age category in years			
40 and younger	8.5	10.1	15.9
41–50	10.6	12.8	16.8
51–60	11.9	14.5	17.0
61–70	13.2	15.7	17.2
71–80	11.4	13.4	14.8
81 and older	9.6	11.9	14.6
Education			
Less than high school	4.4	6.9	7.1
High school graduate	7.8	10.2	12.5
Some college	10.2	13.3	14.8
College graduate	13.7	16.8	19.6
Postgraduate schooling	19.0	21.8	25.3
Annual household income			
Less than $20,000	5.3	8.0	8.6

	All callers (%)	Patients (%)	Family (%)
$20,000–$29,000	6.3	9.6	9.4
$30,000–$39,000	7.7	9.7	12.5
$40,000–$59,000	9.1	10.8	13.9
$60,000–$79,000	12.1	15.7	15.9
$80,000 and greater	14.5	17.5	17.9
Insurance			
No coverage	4.7	7.3	10.8
Any coverage	11.4	12.8	16.0
Year			
2006	10.5	14.9	17.7
2007	9.2	12.4	15.4
2008	8.1	10.2	12.8

Note. There are statistically significant differences, $p < .001$, for all variables for all populations (χ^2 comparison).

Table 3

Logistic regression results showing what factors are associated with the likelihood of having a discussion of clinical treatment trials

	All callers (*n* = 40,661)	Patients (*n* = 14,023)	Family (*n* = 16,678)
Identity of caller			
Nonpatient/family	Ref		
Patient	*5.53 (4.84, 6.32)		
Family member	*6.24 (5.47, 7.12)		
Cancer type			
Prostate and other urogenital	Ref	Ref	Ref
Breast	*0.66 (0.59, 0.75)	*0.64 (0.53, 0.78)	*0.71 (0.59, 0.85)
Colorectal and other gastrointestinal	*1.68 (1.51, 1.87)	*1.58 (1.33, 1.88)	*1.75 (1.51, 2.03)
Hematologic	0.91 (0.80, 1.05)	0.85 (0.68, 1.07)	0.92 (0.76, 1.11)
Skin	*0.67 (0.55, 0.82)	*0.56 (0.41, 0.76)	*0.73 (0.55, 0.96)
Gynecologic	*1.27 (1.11, 1.45)	*1.30 (1.04, 1.63)	*1.24 (1.02, 1.51)
Lung and other respiratory	*1.43 (1.26, 1.61)	*1.54 (1.26, 1.88)	*1.31 (1.11, 1.54)
Head and neck	1.08 (0.91, 1.29)	1.11 (0.83, 1.49)	1.12 (0.89, 1.41)
Melanoma	*2.59 (2.20, 3.04)	*2.28 (1.77, 2.93)	*2.91 (2.34, 3.63)
Other	*1.70 (1.50, 1.92)	*1.65 (1.35, 2.03)	*1.72 (1.46, 2.04)
Spanish language call			
No	Ref	Ref	Ref
Yes	*0.58 (0.40, 0.83)	*0.46 (0.22, 0.97)	0.67 (0.43, 1.04)
Gender			
Male	Ref	Ref	Ref
Female	*0.76 (0.71, 0.82)	*0.77 (0.68, 0.87)	*0.76 (0.69, 0.84)
Race			
White	Ref	Ref	Ref
Black	*0.62 (0.55, 0.68)	*0.66 (0.56, 0.77)	*0.58 (0.51, 0.67)
Other	*0.87 (0.77, 0.99)	0.84 (0.68, 1.05)	0.88 (0.75, 1.03)
Ethnicity			
Non-Hispanic	Ref	Ref	Ref
Hispanic	*0.70 (0.58, 0.85)	0.73 (0.53, 1.02)	*0.72 (0.56, 0.91)
Age category, in years			
40 and younger	Ref	Ref	Ref
41–50	1.06 (0.96, 1.17)	*1.36 (1.09, 1.70)	0.99 (0.88, 1.11)
51–60	*1.14 (1.03, 1.25)	*1.44 (1.17, 1.78)	1.02 (0.90, 1.14)
61–70	*1.16 (1.05, 1.29)	*1.48 (1.20, 1.83)	1.02 (0.90, 1.17)
71–80	0.92 (0.82, 1.04)	1.12 (0.89, 1.40)	0.85 (0.72, 1.01)
81 and older	0.84 (0.70, 1.02)	1.03 (0.77, 1.38)	0.80 (0.59, 1.09)

	All callers (*n* = 40,661)	**Patients (*n* = 14,023)**	**Family (*n* = 16,678)**
Education			
Less than high school	Ref	Ref	Ref
High school graduate	*1.54 (1.31, 1.82)	*1.44 (1.13, 1.84)	*1.71 (1.34, 2.17)
Some college	*2.00 (1.70, 2.36)	*1.98 (1.56, 2.50)	*2.03 (1.60, 2.58)
College graduate	*2.66 (2.26, 3.12)	*2.53 (1.99, 3.21)	*2.74 (2.16, 3.48)
Postgraduate schooling	*3.61 (3.06, 4.26)	*3.39 (2.65, 4.33)	*3.73 (2.93, 4.75)
Repeat caller			
No	Ref	Ref	Ref
Yes	*1.10 (1.01, 1.18)	1.05 (0.93, 1.18)	1.11 (1.00, 1.24)
Year			
2006	Ref	Ref	Ref
2007	*0.85 (0.80, 0.91)	*0.80 (0.72, 0.89)	*0.88 (0.80, 0.96)
2008	*0.69 (0.64, 0.74)	*0.64 (0.57, 0.73)	*0.73 (0.66, 0.81)

Note. Table shows adjusted odds ratio (95% confidence interval) for callers with demographic information. Ref = reference category.

* $p < .05$.

Table 4

Logistic regression results for patients with different types of cancer showing what factors are associated with the likelihood of having a discussion of clinical treatment trials

	Breast cancer (*n* = 4,126)	Prostate cancer (*n* = 1,533)	Colorectal cancer (*n* = 945)	Lung cancer (*n* = 1,141)	Other gastrointestinal cancer (*n* = 758)
Stage of treatment					
New patient	Ref	Ref	Ref	Ref	Ref
Currently in treatment	*1.47 (1.08, 2.00)	*1.80 (1.30, 2.50)	*2.15 (1.24, 3.73)	*1.55 (1.08, 2.23)	*3.28 (2.15, 4.99)
Posttreatment	0.76 (0.52, 1.10)	0.75 (0.44, 1.27)	1.08 (0.55, 2.11)	0.68 (0.36, 1.30)	1.25 (0.63, 2.49)
Recurrence	*2.96 (1.98, 4.44)	*3.55 (2.26, 5.58)	*6.82 (3.47, 13.43)	*3.09 (1.74, 5.46)	*9.31 (5.03, 17.22)
Gender					
Male	—	—	Ref	Ref	Ref
Female	—	—	1.17 (0.79, 1.73)	0.79 (0.57, 1.10)	*0.62 (0.43, 0.89)
Race					
White	Ref	Ref	Ref	Ref	Ref
Black	*0.57 (0.40, 0.80)	0.67 (0.44, 1.04)	*0.40 (0.21, 0.77)	0.63 (0.38, 1.04)	0.75 (0.44, 1.27)
Other	0.81 (0.51, 1.29)	0.58 (0.24, 1.40)	0.91 (0.43, 1.91)	0.66 (0.32, 1.37)	0.68 (0.31, 1.47)
Ethnicity					
Non-Hispanic	Ref	Ref	Ref	Ref	Ref
Hispanic	1.02 (0.55, 1.89)	1.11 (0.41, 3.07)	0.64 (0.18, 2.26)	0.29 (0.04, 2.33)	0.44 (0.14, 1.44)
Age category, in years					
50 and younger	Ref	Ref	Ref	Ref	Ref
51–60	0.84 (0.63, 1.12)	2.19 (0.82, 5.89)	1.49 (0.87, 2.55)	1.27 (0.76, 2.11)	0.96 (0.58, 1.58)
61–70	0.93 (0.69, 1.24)	1.61 (0.61, 4.27)	1.48 (0.87, 2.51)	1.08 (0.66, 1.78)	1.13 (0.68, 1.88)
71–80	*0.46 (0.29, 0.72)	1.54 (0.58, 4.12)	0.71 (0.37, 1.38)	0.88 (0.52, 1.50)	0.86 (0.49, 1.52)
81 and older	*0.30 (0.12, 0.76)	1.59 (0.56, 4.56)	0.44 (0.16, 1.17)	1.15 (0.47, 2.81)	0.64 (0.26, 1.59)
Education					
Less than high school	Ref	Ref	Ref	Ref	Ref
High school graduate	*2.26 (1.02, 5.05)	0.73 (0.38, 1.38)	*4.01 (1.17, 13.80)	1.52 (0.82, 2.83)	2.13 (0.85, 5.32)
Some college	*3.78 (1.74, 8.25)	0.88 (0.48, 1.61)	*6.47 (1.91, 21.89)	*2.65 (1.44, 4.88)	1.88 (0.76, 4.67)
College graduate	*5.61 (2.57, 12.24)	0.98 (0.53, 1.83)	*6.87 (2.00, 23.59)	*3.04 (1.59, 5.80)	*2.55 (1.01, 6.46)

	Breast cancer (*n* = 4,126)	Prostate cancer (*n* = 1,533)	Colorectal cancer (*n* = 945)	Lung cancer (*n* = 1,141)	Other gastrointestinal cancer (*n* = 758)
Postgraduate schooling	*6.23 (2.82, 13.78)	1.40 (0.75, 2.61)	*11.21 (3.18, 39.54)	*3.55 (1.76, 7.15)	*5.50 (2.14, 14.13)
Repeat caller					
No	Ref	Ref	Ref	Ref	Ref
Yes	1.06 (0.82, 1.39)	0.96 (0.68, 1.36)	0.83 (0.51, 1.37)	1.06 (0.70, 1.60)	0.64 (0.38, 1.09)
Year					
2006	Ref	Ref	Ref	Ref	Ref
2007	*0.77 (0.60, 0.99)	0.92 (0.66, 1.28)	0.96 (0.63, 1.47)	0.70 (0.49, 1.02)	0.79 (0.52, 1.18)
2008	*0.58 (0.44, 0.78)	*0.67 (0.47, 0.98)	0.62 (0.38, 1.02)	0.71 (0.48, 1.05)	*0.53 (0.33, 0.85)

Note. Table shows adjusted odds ratio (95% confidence interval). Table includes only callers with demographic information. The variable for Spanish language could not be included because of low sample sizes when cancers were analyzed separately. Ref = reference category.

* $p < .05$.