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Involving American Indians and medically underserved rural populations in cancer clinical trials

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Abstract

Purpose—To assess cancer clinical trial recruitment and reasons for nonaccrual among a rural, medically underserved population served by a community-based cancer care center.

Methods—We prospectively tracked clinical trial enrollment incidence among all new patients presenting at the Rapid City Regional Cancer Care Institute. Evaluating physicians completed questionnaires for each patient regarding clinical trial enrollment status and primary reasons for nonenrollment. Patients who identified as American Indian were referred to a program where patients were assisted in navigating the medical system by trained, culturally competent staff.

Results—Between September 2006 and January 2008, 891 new cancer patients were evaluated. Seventy-eight patients (9%; 95% confidence intervals, 7–11%) were enrolled on a clinical treatment trial. For 73% (95% confidence intervals, 69–75%) of patients (646 of 891) lack of relevant protocol availability or protocol inclusion criteria restrictiveness was the reason for nonenrollment. Only 45 (5%; 95% confidence intervals, 4–7%) patients refused enrollment on a trial. Of the 78 enrolled on a trial, 6 (8%; 95% confidence intervals, 3–16%) were American Indian. Three additional American Indian patients were enrolled under a nontreatment cancer control trial, bringing the total percentage enrolled of the 94 American Indians who presented to the clinic to 10% (95% confidence intervals, 5–17%).

Limitations—Eligibility rates were unable to be calculated and cross validation of the number in the cohort via registries or ICD-9 codes was not performed.

Conclusion—Clinical trial participation in this medically underserved population was low overall, but approximately 3-fold higher than reported national accrual rates. Lack of availability of protocols for common cancer sites as well as stringent protocol inclusion criteria were the primary obstacles to clinical trial enrollment. Targeted interventions using a Patient Navigation program were used to engage AI patients and may have resulted in higher clinical trial enrollment among this racial/ethnic group.

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Introduction

Cancer clinical trials offer patients the opportunity to receive state-of-the-art treatments to improve cancer-related health outcomes. Emerging technologies that are often only available and, at least early on implementation, best administered through clinical trials may improve not only cancer control outcomes, but improve quality of life or shorten treatment times (e.g., shortened-course radiation therapy) and thus the overall burden of a life-threatening illness. The advancement of such research and recognition of the importance of broad, diverse inclusion in such efforts by all population subgroups found Congressional support in 1993 with the National Institutes of Health (NIH) Revitalization Act which stipulated that efforts should be made to include women and minority patients in NIH-sponsored research [1]. Since that time, analyses of clinical trial participation have shown clinical trial enrollment rates of ~3%, both nationwide as well as in studies from regional centers [2–4]. Furthermore, studies continue to indicate lower rates of clinical trial enrollment among minority, rural, and low socioeconomic subpopulations [2–8]. Discrepancies in participation in clinical trial opportunities may exacerbate known cancer-related health disparities among underserved populations [9–11].

Cancer-related mortality rates among American Indians and, specifically among American Indians in the Northern Plains region of the U.S., are among the highest of all racial/ethnic groups [11–14]. Underlying causes for this disparity are multiple; and some factors, such as mistrust of doctors and hospitals, dissatisfaction with prior health care received, [15] and burden of traveling long distances to receive specialized medical care have been recently documented [10,16]. Cancer treatment regimens often involve multiple modalities and, when radiation therapy is recommended can require weeks of daily treatment. Advances in radiation therapy have evolved to offer shortened-courses of treatment, which may be more feasible for American Indian patients who are rurally located and/or reservation-based. However, many of these treatments are still offered on protocols as they often employ new technologies or radiation dose fractionation schedules that are potentially riskier than standard radiation therapy. Most of these protocols are available only at large academic cancer centers or in urban medical centers. Furthermore, American Indian patients are among the most underrepresented reports on clinical trial enrollment by race/ethnicity, [2,4,7,17] and are enrolled at rates disproportionately lower than their percentage of the U.S. population. [2]. Despite the fact that this remote, resource-challenged population might benefit from advances in radiation therapy delivery, little is known about the feasibility of clinical trial implementation among this population.

In recognition of these issues as well as the challenges faced by the rural and minority populations it serves, Rapid City Regional Hospital's Cancer Care Institute undertook a comprehensive cancer control effort that introduced clinical trials into a regional cancer care network. Rapid City Regional Hospital is the secondary and tertiary oncology care provider to a large population of American Indians in western South Dakota and the surrounding areas; ~60,000 adult American Indians are serviced by this center. In 2002, our institution was awarded a Cancer Disparities Research Partnership grant to address the causes of cancer-related disparities among American Indians, and accrual of American Indian patients to cancer clinical trials was the mandated centerpiece of this grant initiative. Since that time, a multifaceted, community-based participatory research and intervention effort has been undertaken targeting the American Indian community in our region [10,18–20]. Furthermore, according to the Index of Medical Underservice, [21] the entire population of western South Dakota, where Rapid City Regional Hospital's CCI is located is considered underserved. Therefore, while many clinical trials opened at our institution were Cancer Disparities Research Partnership program-driven and thus focused on American Indians, an active program to enroll both American Indian and non-American Indian patients has ensued. Prior to the initiation of this program, limited

infrastructure for clinical trial participation existed in this region: less than 4% of patients and virtually no American Indians were enrolled on clinical trials. The goal of this analysis is to report upon our prospective analysis of clinical trial accrual and primary reasons for nonparticipation in a rural, community hospital setting where extensive efforts have been made to enroll underserved patients on cancer clinical trials.

Methods and population

All patients presenting for an initial evaluation at Rapid City Regional Hospital Cancer Care Institute, Rapid City, South Dakota, were eligible for inclusion in this analysis. Rapid City Regional Hospital serves as the major secondary and tertiary cancer services provider for the Oglala Sioux Tribe (Pine Ridge), Cheyenne River Sioux Tribe, Rosebud Sioux Tribe, and the Rapid City American Indian population, and all American Indian patients came from these communities. The Rapid City Regional Hospital's Investigational Review Board granted approval to conduct the study. Clinical trial accrual was prospectively monitored from September 2006 through January 2008. The primary reason for nonparticipation in a clinical trial was tracked for each patient. Rapid City Cancer Care Institute has primary membership and access to clinical trials through the North Central Cancer Treatment Group. The center also has clinical trial access as an affiliate of the Radiation Therapy Oncology Group, Eastern Cooperative Oncology Group, National Surgical Adjuvant Breast and Bowel Project, Gynecologic Oncology Group, and Cancer Therapy Evaluation Program. In addition, cancer treatment trials were written for prostate and breast cancer under the auspices of the Cancer Disparities Research Partnership grant. During the time of evaluation approximately 75 clinical trials were open.

We developed an administrative and research infrastructure that supports both patients and physicians in an effort to increase clinical trial participation. All American Indian patients presenting to the cancer center were eligible to participate in a grant-sponsored patient navigation program [19,20]. Through this program, American Indian cancer patients were offered services through a program where patients were assisted in navigating the medical system by trained, culturally competent staff to serve as advocates through the cancer care continuum starting with presentation for evaluation and treatment. The patient navigators assist with coordinating appointments, following up on tests, obtaining medications and specialty services or devices, facilitating transportation and lodging, and offering social support during treatment. Community research representatives embedded in the American Indian communities provide cancer education, network with local heath resources, collect survey data, and develop liaisons between the cancer center and tribal governments. Patient education materials were translated into the Lakota language. The cancer center staff members involved in this effort are either closely connected with or members of the American Indian communities served by this program, and one staff member is a trained Lakota medicine man. This program has been described in detail elsewhere [19,20]. Furthermore, we received a Clinical Trials Operating Committee (CTOC) supplement grant in September 2006 (5U56CA99010-06S2) with the goal of increasing patient recruitment (both non-AI and AI) to clinical trials). One dedicated research nurse and one dedicated research associate were hired as part of that effort to network and expand current outreach programs for clinical trial accrual.

Three radiation oncologists and three medical oncologists were evaluating patients in this cancer center during this time period. Physicians were made aware of protocol availability through the clinical research associates, frequent e-mails, weekly tumor board discussion, and monthly distribution of open protocols. In addition, each chart was screened by research staff prior to the physician consultation for potential protocol eligibility. The evaluating physician was asked to complete a datasheet indicating clinical trial eligibility, whether the patient was enrolled to a trial, and the primary reason for nonenrollment if the patient was not accrued on

to a clinical trial. The data collected through this included limited patient demographics and description of cancer site with stage at presentation. Data was de-identified and entered into a SPSS database (Apache Software Foundation). Confidence intervals (CI) were calculated, and differences between proportions for categorical variables were analyzed using the chi-square statistic or Fisher's exact test as appropriate. Race was self-reported by the patient.

Results

Between September 2006 and January 2008, 903 new patients presented to RCRH Cancer Care Institute and were evaluated for participation in a clinical trial. Twelve of these patients did not have a cancer diagnosis. Therefore, 891 patients were included in this analysis. The median age was 67 years (range, 19–92 years). Seventy-nine percent of patients were white ($n = 791$), 11% ($n = 94$) were American Indian, and <1% of the patients were Hispanic, African American, Asian, or of other racial/ethnic background (Table 1). A summary of the primary site of malignancy is shown in Table 2.

Physician triage for trial consideration

For 112 (13%) patients, a clinical trial was not considered by the evaluating physician. The primary reasons were: patient not returning for further treatment, 27 (3% of 891); previous therapy, 25 (3%); synchronous primary malignancy, 21 (2%); unknown primary site, 20 (2%); poor performance status, 12 (1%); no further treatment recommended, 3 (<1%); no evidence of disease, 2 (<1%); other reasons, 2 (<1%).

Clinical trial participation, protocol availability, eligibility criteria, and restrictiveness

Physicians considered a clinical trial in 779 (87% of 891) patients. Seventy-eight (9%; 95% CI, 7–11%) patients were placed on a clinical treatment trial. Of the 779 considered for trial enrollment, 701 were not placed on a clinical treatment trial. For 646 (73%; 95% CI, 69–75%) patients, disease presentation specifics and protocol-related restrictions precluded enrollment on a clinical trial. The primary reasons were as follows: trial not appropriate/physician judgment, 202 (23%), patient not eligible due to stage at presentation, 171 (19%) (of these 145 presented with stage too advanced/metastatic disease and 26 presented with stage too early for trial eligibility); no protocol available for tumor site, 134 (15%); patient ineligible due to factors other than stage or performance status, 120 (13%); co-morbidities/age, 19 (2%). Therefore, for 83% (646 of 779) of those considered for clinical trial enrollment, protocol availability, disease and patient presentation factors, and trial restrictiveness/appropriateness prevented enrollment on a clinical treatment trial.

Patient-related factors and participation refusal

Of the 701 patients considered for clinical trial, but not enrolled on a trial, patient related factors precluded enrollment in 55 (6% of the total cohort, 55/891). The primary patient-related reasons for nonenrollment were as follows: patient refused/preferred standard treatment or no treatment, 45 (5%); insurance denied coverage for treatment on clinical trial, 6 (<1%), and patient resided prohibitively far from the clinic and was logistically unable to participate in clinical trial, 4 (<1%). A summary depiction of the analysis of clinical trial enrollment and reasons for nonenrollment is depicted in Figure 1.

An analysis of whether a patient refused clinical trial participation by race was performed. There was no significant difference by race in the proportion of patients, who refused clinical trial participation. This was true whether race was dichotomized as white versus non-white, 5% (95% CI, 4–7%) versus 4% (95% CI, 0.2–8%) refusing participation, respectively ($p = 0.42$); or whether race was dichotomized as American Indian versus non-American Indian, 4% (95% CI, 1–11%) versus 5% (95% CI, 4–7%) refusing participation, respectively ($p = 0.48$).

American Indian clinical trial participation

Of the 94 American Indian patients evaluated, 6 (6%; 95% CI, 3–14%) were placed on a clinical treatment trial. Thus, 8% (95% CI, 3–16%) of all 78 patients enrolled on a clinical treatment trial were American Indian. For the 88 American Indian patients, who were not enrolled in cancer treatment trials, the primary reasons for nonenrollment were as follows: advanced stage/poor performance status/co-morbidities, 24 (27%); no protocol for tumor site, 21 (24%); other reasons for ineligibility after evaluation, 20 (23%); physician judgment/trial treatment not appropriate, 18 (20%); patient refused/preferred standard treatment/preferred no treatment, 4 (4%); and contract health coverage (through the Indian Health Service) denied trial treatment coverage, 1 (1%). Additionally, three (3%) American Indian patients were enrolled on a cancer control/nontreatment trial involving analysis of potential ataxia telangectasia gene mutations among American Indians. Thus, the total number of American Indian patients enrolled on a cancer treatment or control protocol was 9 (10%; 95% CI, 5–17%). All American Indian patients enrolled on clinical trials underwent patient navigation.

Discussion

In this assessment of clinical trial accrual among cancer patients presenting to our center which serves a large American Indian population, we report a clinical treatment trial accrual proportion of 6% (95% CI, 3–14%) among American Indian cancer patients. When we include rates of accrual to a race-specific, nontreatment cancer control trial (ATM gene mutation study), the total cancer trial enrollment proportion among American Indian patients is 10% (95% CI, 5–17%) for our institution. This compares favorably with other studies that have reported American Indian trial accrual rates of <1% [2,4,7,17]. Furthermore, we show a 9% (95% CI, 7–11%) proportion of clinical trial enrollment among all patients (regardless of race/ethnicity) presenting to this regional, community-based cancer center.

The primary reasons for nonenrollment in clinical trials related to lack of availability of protocols and protocol inclusion criteria restrictiveness. These reasons are similar to those reported by other investigators in community settings [3]. However, limited trial enrollment due to a paucity of trials is not a problem limited to rural or community settings. Investigators in academic centers have reported similar obstacles [22,23] and have suggested that lack of trial availability is one of the factors that underpins low accrual of underrepresented populations to cancer clinical trials. This is especially relevant to our population, when considering that many protocols were not available for advanced-stage disease in combination with fact that American Indians present disproportionately at more advanced stages of cancer [10,12,24]. Similarly, protocol inclusion criteria restrictiveness has also been shown by other investigators to be a barrier to trial participation, especially among underrepresented populations [25]. The overarching theme of reasons for low trial accrual in ours and similar studies is that currently available cancer clinical trials are not designed to meet the cancer care needs of our underserved population. Reasons for nonenrollment in studies are multiple, but often include poor performance status, advanced stage of disease, and trial restrictiveness. The cooperative groups may need to increase awareness of these factors when designing clinical trials and eligibility criteria. In other words, trials are needed for common disease sites in which the majority of patients seen in a typical cancer center would be eligible for study, in order to establish safety and efficacy of advances in treatment for community practice populations.

Investigations into effective strategies for recruiting underrepresented populations to cancer clinical trials are needed [23,25,26]. Socio-cultural factors and mistrust may play a role in hindering efforts to engage minority populations in research-related treatment regimens [8, 27–30]. A recent investigation among cancer patients in this region revealed that American Indian patients exhibit higher levels of medical mistrust and higher levels of dissatisfaction with previous health care compared to their white counter parts [15]. These findings corroborate

those of others suggesting that mistrust may play a role in hindering efforts to engage American Indians in clinical research [28]. Little published data exist on successful trial recruitment programs, perhaps reflecting the heterogeneity of underserved populations, e.g., what works in one vulnerable or underserved population may not serve another as well [26)]. Even fewer studies specifically report upon American Indian patient participation on cancer clinical trials. American Indians experience poorer cancer related health outcomes relative to other racial and ethnic groups, [11–14,31] and a recent report on the status of cancer by the Center for Disease Control showed that mortality trends have declined for all racial groups except American Indians [11]. This suggests that the advancements in cancer control and treatment that are improving outcomes on a national level are not reaching American Indian populations.

Patient navigator programs such as the one implemented at our institution may provide the culturally competent avenue to more actively engage this and other vulnerable populations in the cancer control and care continuum, including clinical trial participation [18–20,32–35]. A major accomplishment of our Cancer Disparities Research Partnership program has been the establishment of trust within the American Indian communities on three reservations [16]. There are two patient navigation programs, one ‘embedded’ at the community level and one within the cancer center. The patient navigation programs emphasize cancer screening and education, as well as clinical trial participation. These efforts have increased visibility and trust and thus, at least in part, may be responsible for the higher rates of American Indian enrollment on clinical trials. Due to the embrace of and enthusiasm for patient navigation among the American Indian population, we have implemented patient navigation for all breast cancer patients (including non-American Indian patients), and will be expanding to other disease sites as well. Implementation of the CTOC grant has also increased clinical trial awareness through physician networking and dedicated research staff, and greatly assisted in attaining higher accrual rates to clinical trials.

While developing patient and physician networking infrastructure as we did may have helped increase clinical trial recruitment in our community-based cancer center situated in an underserved region, other solutions may warrant consideration by the research/cooperative-group community. Increase in the number of clinical trials available for common disease sites at various stages of presentation would expand options for patients and providers. However, we recognize that a call for expansion in the number of clinical trials offered may meet constraints in the current research funding climate, [36] or may possibly detract from scientific purity and rigor needed to establish causal relationships in evaluation of interventions [37]. Another consideration may be to increase the number of phase II trials designed for limited-access populations. In our experience serving a rural-based, socio-economically challenged population, we had difficulty in accruing patients to phase III trials involving emerging technologies where treatment times may be shortened such as with short-course radiation therapy regimens. When presented with an option for treatment regimens with lower time burden versus weeks of protracted standard therapy, many patients simply opt for the shortest course of treatment rather than risk randomization to a longer regimen. While we understand that phase III data form the bedrock of the rationale for management in cancer care, perhaps more phase II trial availability could broaden applicability of non-phase III trial results and include more diverse populations.

We acknowledge that our study has several limitations. For example, for this analysis we were unable to calculate eligibility rates. Developing a research culture and infrastructure in our institution is an ongoing effort, and we experienced logistical constraints in trying to bridge the clinical and research efforts in this community-based, regional hospital that historically did not have research as part of its mission. If patients were deemed unsuitable for clinical trial by a physician and no eligibility-related data were scored on the datasheet, then no further data could be collected by the research staff as the patient had not consented to have there data

reviewed for research purposes. Furthermore, we were unable to cross validate our overall cohort size with registries or ICD-9 codes to assure that we had complete accounting of new cancer cases. This may have introduced some error into our sampling. Efforts to increase research staffing and to improve capture of data are ongoing.

In conclusion, our efforts to increase cancer clinical trial enrollment in a community-based, rural cancer center that provides care for underserved populations yielded clinical trial enrollment percentages that, while low, were higher than reported national rates of clinical trial participation. Our biggest hurdle to trial accrual seemed to be that the available trials were not designed for our patient population. However, we were able to recruit a relatively higher proportion of American Indian patients to clinical treatment and control trials than seen in other studies. This may be in part due to our efforts to develop culturally and linguistically specific outreach to patients in our region as well as involve American Indian community members in the implementation of our outreach. More research is needed into developing strategies, perhaps such as patient navigation or culturally specific community outreach, as means to engage vulnerable populations in the cancer care continuum. We are currently implementing metrics to specifically evaluate efficacy of interventions such as the patient navigation program in hopes that any successful strategies mitigating barriers to care or engaging patients in clinical trials could be applied to American Indian or other vulnerable populations in other regions. Our effort suggests that local community-based cancer centers can be enlisted as partners in furthering a cancer research agenda. Our findings also highlight the need for increased availability of cancer treatment protocols for common disease sites as well as designs that are inclusive of a broad and diverse population.

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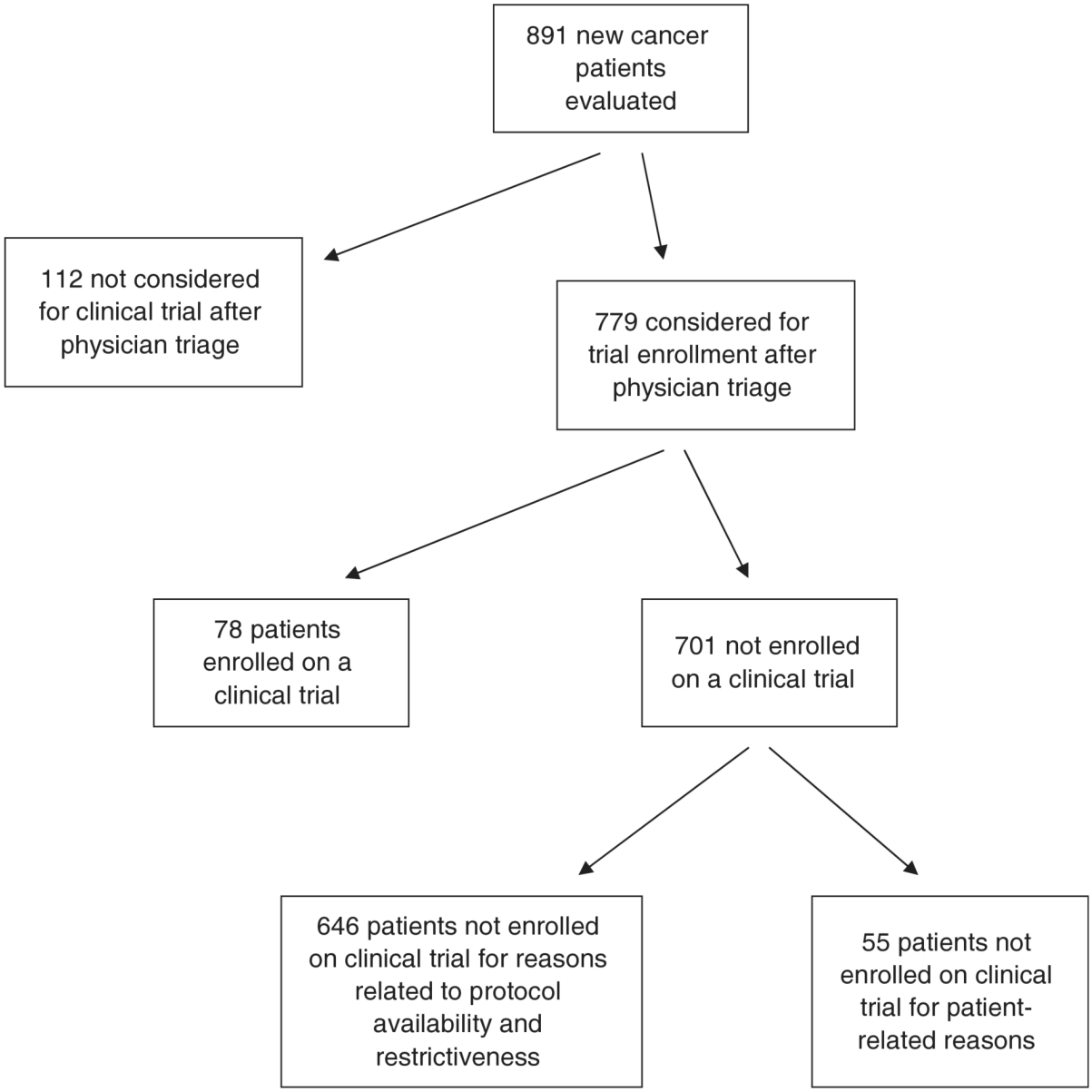

Figure 1.
Analysis of clinical trial enrollment and reasons for nonenrollment

Table 1

Patient characteristics (*n*= 891)

Characteristic	No.	(%)
Sex		
Male	446	50
Female	445	50
Age		
Median	67	
Range	19–92	
Race		
Caucasian	791	89
American Indian	94	11
Hispanic	1	<1
African American	1	<1
Asian	2	<1
Other	2	<1

Table 2

Cancer specific characteristics of the cohort

Site/primary malignancy	No.	(%)
Breast	186	21
Prostate	158	18
Lung	127	14
Hematologic	90	10
Colo-rectal	68	8
Head and neck	54	6
Gynecologic	46	5
Gastric	42	5
Skin	32	4
Nonprostate GU	27	3
CNS	19	2
Bone/soft tissue sarcoma	11	1
Hepatobiliary	6	<1
Other	7	<1
Unknown primary	18	2