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Addressing clinical trials: Can the Multidisciplinary Tumor Board improve participation? A study from an academic women's cancer program*

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Abstract

Objective—The Tumor Board (TB) allows for an interdisciplinary approach to cancer treatment designed to encourage evidence-based treatment. However, its role in facilitating clinical trial participation has not been reported. We aimed to determine whether a prospective TB is an effective strategy for trial recruitment and to identify steps within the TB process that facilitate discussion of trial eligibility and optimize accrual.

Methods—We conducted a retrospective cross-sectional analysis of women presented to Gynecologic Oncology TB between March and December 2008. Patient demographics, TB recommendations, and post-TB patient discussions were abstracted. These were compared to data derived from the Department of Oncology Research to determine research team awareness of eligible patients and confirm trial enrollment(s). Data analysis was completed with Chi-square test; risk ratios and confidence intervals were calculated as summary measures.

Results—We reviewed 1213 case presentations involving 916 women. Overall, 358 TB recommendations (30%) identified eligible patients, of which enrollment consisted of 87 (24%) trials (6% therapeutic trials and 18% non-therapeutic trials). Compared to other types of TB recommendations, those involving trials were discussed less frequently at post-TB patient visits (79% vs. 44%). Documentation of trial discussion at the post-TB visit was more likely to result in trial participation, versus solely relying on the research staff to communicate enrollment eligibility with the treating team (RR 2.5, $p = 0.006$).

Conclusions—Patients identified by the TB were 2.5-times as likely to enroll in a clinical trial, but trials were mentioned only 44% of the time. Interventions that facilitate trial discussions during post-TB meetings are needed to improve trial participation.

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Conflict of interest statement

The authors declare that there are no conflicts of interest.

Keywords

Tumor board; Clinical trials; Gynecologic oncology; Ovarian cancer; Endometrial cancer; Cervical cancer

Introduction

The Tumor Board (TB) is a multidisciplinary conference that incorporates radiologists, pathologists, surgeons, radiation oncologists, and medical oncologists where individual patient cases are reviewed with the aim to provide evidence-based management recommendations. Currently the American College of Surgeons (ACOS) Commission on Cancer (CoC) requires multidisciplinary TB conferences at each of its approved hospital cancer programs and establishes standards to ensure quality control [1]. The CoC currently requires that 10% of an institution's annual caseload be discussed each year and at least 75% of the cases be presented prospectively to ensure an effective role in patient management. Hospital TB conferences have been an accepted part of cancer care for well over 50 years [2], with the benefits of a multidisciplinary discussion extending to patient care [3–5], changes in surgical management [6], staff education [7–9], collaboration among physicians [7], limitation of liability [8], and enrollment in protocols [8,10].

Unfortunately, with regards to the latter, only 2–4% of adult cancer patients in the United States participate in National Cancer Institute (NCI)-sponsored treatment clinical trials, a rate that has not improved in almost 2 decades [11,12]. With recommended target participation rates between 10% and 15% [13], low patient accrual to trials has prompted a wide spectrum of efforts, including legislation reform (e.g. enactment of the National Institutes of Health Revitalization Act in 1993 to ensure inclusion of women and minorities in clinical research) and increased NCI budget for research funding. Potential physician, patient, and system barriers to cancer clinical trial enrollment have previously been characterized [12,14–16]. Some factors specific to gynecological oncology include the relatively low incidence of some diseases (e.g. vulvar cancer) and strict clinical trial inclusion criteria for disease stage severity [17].

Few studies have investigated the impact of multidisciplinary TB conferences on patient accrual in cancer clinical trials, and even fewer have been conducted within the field of gynecologic oncology [5,10]. Therefore, we sought to address the impact of the TB on clinical trial accrual by examining the impact of the multidisciplinary Gynecologic Oncology TB on clinical research at our academic women's oncology program. The Program of Women's Oncology is the state's largest cancer center dedicated to women, receiving referrals from local clinics and private offices across southern New England. Off-site serviced areas include Fall River and South County Commons, both within Rhode Island as well as Cape Cod, Massachusetts and New London, Connecticut. The Gynecologic Oncology TB includes participation from all nine board-certified/eligible gynecologic oncologists and three medical oncologists working alongside two radiation oncology groups and pathology and radiology divisions at Women & Infants' Hospital specialized in women's health. Over 90% of all newly diagnosed gynecologic oncology patients are presented at the

Tumor Board. It is a full member of the Gynecologic Oncology Group (GOG), the NCI funded cooperative group specializing in clinical research in gynecologic oncology.

We hypothesized that patients were appropriately receiving TB recommendations regarding trial availability, but were subsequently less likely to have a post-TB discussion with their physician regarding trial eligibility compared to other TB recommendations.

Materials and methods

Prior to the initiation of the study, all procedures were reviewed and approved by the Institutional Review Board. Data for this study were derived from patients who were presented at the Program of Women's Oncology weekly, prospective, and multidisciplinary TB at Women & Infants' Hospital, Providence, Rhode Island. If a woman was presented to TB more than once, (i.e., with a different/new diagnosis of cancer), we captured this data under separate study ID's where each presentation would be considered as an individual TB presentation, though still considered as referring to one patient.

Specific data collected included demographics and tumor-specific information (histologic diagnosis, stage, surgical outcome), number of TB presentation(s) (1st vs. 2nd vs. multiple), and specific recommendations made. TB recommendations were classified as surgery, chemotherapy, radiation therapy, endocrine treatment, clinical trial eligibility, referral to the Cancer Risk Assessment & Prevention Program for genetic counseling, referral to the Clinic for Sexuality, Intimacy and Fertility, no treatment and/or further workup. We also collected TB recommendations that included referral to specialty consultation, TB re-presentation, or were otherwise unspecified.

Patient charts and dictated notes were reviewed to assess whether TB recommendations were discussed with patients and if they were subsequently implemented. Data on patient enrollment into clinical trials were retrieved from physician notes and confirmed by cross-referencing each patient with the Department of Research enrollment list. Cases presented by community physicians and those not followed at the Program in Women's Oncology were excluded from subsequent analysis. A flow chart of the TB process, from initial presentation to final recommendation(s) and subsequent physician discussion is shown in Fig. 1. As part of this process, patients identified by TB for trial participation are tracked by research staff who regardless of physician follow-up at the post-TB discussion, also approach the treating physician(s) to make them aware of pertinent eligible trials.

To determine the impact of TB recommendations on trial accrual, we specifically restricted our analysis to only those patients who received a TB recommendation for clinical trial eligibility. The trial enrollment rate was calculated by dividing the total number of trial enrollments by the total number of TB recommendations. In addition, we specifically calculated the percentage of patients enrolled in therapeutic trials among all cancer patients during our study period, again excluding all referrals from community physicians.

Variables were compared by Chi-square test or McNemar's test. Risk ratios (RR), difference in proportions, and their corresponding 95% confidence intervals (CIs) were calculated as

summary measures. Two-tailed p -values were reported with $p < 0.05$ considered statistically significant. Data analysis was performed with STATA 9.0 (StataCorp, College Station, TX).

Results

We reviewed 1213 presentations from 40 TB conferences conducted between March 18, 2008 and December 30, 2008. There were 794 (65%) first presentations, 365 (30%) second presentations, and 54 (4%) multiple presentations, which involved 916 patients. Table 1 provides a summary of our patient demographics. Median age of patients presented was 57 (range, 16 to 95). Ninety percent were white, 3% African American, 1% Asian, and 6% unspecified/other race. Table 2 describes the composition of diagnoses by disease site that were reviewed at TB. Endometrial cancer was the most common diagnosis (40%), followed by ovarian (23%), and cervical cancers (15%).

Thirteen percent of all TB recommendations noted patient eligibility for a clinical trial(s). Compared to other recommendations, it was the fourth most commonly cited (Table 3, Fig. 1). Other TB recommendations, in descending order, were as follows: surgery (22%), further work-up (22%), no treatment (19%), chemotherapy (13%), radiation treatment (6%), referral to the Cancer Risk & Prevention Program (3%), and endocrine/hormonal therapy (2%). Patients were identified for inclusion in diagnostic studies in 65% of cases; therapeutic studies were identified for 32% of patients presented. Regarding organ-specificity, the majority of patients were eligible for either an endometrial study (39%) or ovarian cancer trial (29%). Table 4 summarizes the overall distribution of eligible patients for specific tumor sites and for specific trial types (diagnostic, therapeutic or prognostic).

Restricting subsequent analyses to those patients who received care within the Program of Women's Oncology, we found documentation of a formal post-TB discussion between physician and patient in 67% of cases. However, for cases in which the TB recommended trial consideration, we could find discussion relevant to trials in only 44% of post-TB discussions, which is significantly lower compared to documented discussion on other TB recommendations made (RR 0.55, $p < 0.0001$, 95% CI 0.59–0.63). Interestingly, we found that having physicians discuss trial recommendations stemming from the TB was associated with a significantly higher rate of recruitment to trials when compared to the sole reliance on research staff for clinical trial accrual (44% vs. 25%, $p < 0.001$) (Fig. 2).

Of the 358 TB recommendations stating patient eligibility for a clinical trial, 87 patients were ultimately enrolled, for an overall accrual rate of 28%. When this analysis was restricted to enrollment in *therapeutic* trials, the accrual rate was 6%. Again, compared to reliance solely on research staff for recruitment, patients were 2.5 times more likely to participate in a clinical trial(s) if post-TB discussion of trials was documented (RR 2.5, $p = 0.006$). Those patients who had a post-TB discussion with their physician and were also tracked by the research team were significantly more likely to be enrolled in a clinical trial than either group alone (physician discussion—RR 1.4; $p = 0.02$; research team—RR = 3.5; $p < 0.0001$).

Of note, there were 11 patients whose physicians appropriately identified them to be eligible for a clinical trial and discussed this option despite lack of documentation in the TB recommendations. Two of the 11 patients subsequently enrolled in a clinical trial.

Discussion

Low patient accrual to clinical trials is an important public health concern because results from such studies have potential to positively impact clinical management and outcomes. For example, clinical trials expand the number of treatment options available to cancer patients, providing access to new therapeutic approaches that may otherwise not be available on the market. They also help to further elucidate the natural history of malignant disease, allowing for more sensitive/specific diagnostic tools and targeted interventions. Therefore, to optimally manage cancer patients, it is critical to address specific issues related to clinical trial availability and low enrollment rates [11,12].

In our review of 1213 GOTB presentations from March to December 2008, 358 recommendations included patient eligibility for a clinical trial(s). This led to an overall accrual rate of 28%. Six percent of the 419 cancer patients participated in a therapeutic clinical trial, which is slightly increased from the 2–4% annual enrollment rate of NCI-sponsored treatment trials. Whether this national statistic is an optimal rate for comparison or the 10–15% goal previously established in the literature is a different question altogether and remains unanswered.

Post-TB discussions between physicians and patients were 45% less likely to include trial eligibility than any other recommendations. This not only highlights an area within the TB process where targeted interventions may help increase trial accrual, but it also raises other important considerations regarding optimal trial accrual. Specifically, what decision-making processes do physicians consider when deciding whether or not to offer a clinical trial to their patients? Mannel et al. [18] investigated physician trial enrollment at a single institution and found that senior faculty had a higher rate of enrollment than junior faculty (71% vs. 31%) and similarly those faculty who were principal investigators were more likely to enroll. Availability of patients, patient variances, support staff, and institutional commitment were deemed secondary to physician factors in regards to successful enrollment on clinical trials. These results also warrant further quality assurance studies to evaluate whether enrollment rates reflect appropriate referrals to clinical trial rather than individual physician referral habits.

Although our findings are specific to the TB process, they reiterate important patient, physician, and system barriers to clinical trial accrual that have previously been published [19,16]. Grunfeld et al. [14] conducted a qualitative study of the perspective of clinical research associates suggesting system factors have the greatest impact on ability to accrue. Specific barriers described included the following: trial and pharmaceutical company requirements (i.e. documentation), as well as busier clinics which imposed conflict between work demands, and time taken out to accrue patients. In contrast, they also studied facilitators to clinical trial enrollment in clinical trials and reported that patients seem more knowledgeable about trials than they have in the past. Even more encouraging is the

consistency of this finding with other studies that show patients are willing to learn about clinical trials as well as participate in them if approached appropriately by a physician [20,21].

Other facilitators to enrollment in cancer clinical trials have been characterized by Sateren et al. [22] who reported the number of oncologists ($p = 0.04$) and the presence of approved cancer programs ($p < 0.0001$) were both significantly associated with increased enrollment rates. Whether these associations can be attributed to the multidisciplinary TB process remains unanswered. This limitation in conjunction with previously reported system barriers to trial accrual highlights the value of our study. Not only do we elucidate the potential for multidisciplinary TBs to optimize clinical trial enrollment, but we also sought to address specific areas within the TB process where interventions are most needed.

Our study has several limitations. Given our 42-week study period, we were not adequately able to compare our patient accrual to that of the annual rate of NCI-treatment trials nationwide. In addition, we were unable to determine if a discussion regarding clinical trials took place in the absence of documentation. However, given that this limitation only applied to 6 cases, we do not feel that this significantly alters our results. Further, no data were available on patients who were directly referred to TB by a community physician, nor did we assess physician and patient barriers to enrollment. Finally, the majority of presentations concerned first presentations of women with suspected or newly diagnosed cancers. Thus, the opportunities for identification of women with advanced or metastatic disease for trials by the TB process is not adequately addressed in the scope of this study.

Cancer clinical trials are an important cornerstone to bridging our knowledge of the natural history of malignant disease and clinical practice. Not only do they provide an effective means of evaluating new diagnostic, therapeutic, and prognostic agents, but some studies, although controversial, have shown participation in trials is not harmful [23] and has potential to improve clinical outcomes [24]. Djubegovic et al. [25] found that 30% of trials had statistically significant results, 80% of which new interventions were superior to the standard of care. This study also confirmed a pattern of trial successes that has become more stable overtime, estimating that 25% to 50% of new cancer treatments that reach phase 3 randomized clinical trials will prove successful. Therefore, it is important to make appropriate referrals to clinical trials to optimize the benefits for individual study participants without compromising the power or generalizability of results to the target population at whole.

Future efforts should focus on interventions that aim to: (1) improve post-TB discussions between physicians and patients to incorporate all recommendations, especially eligibility for clinical trials; (2) identify and improve system, physician, and patient barriers to trial enrollment; (3) use clinical research assistants in the TB process to optimize accrual; and (4) further investigate the role of community physicians within the TB process. We propose such interventions with the hope of improving the TB process, optimizing cancer clinical trial accrual, and ultimately enhancing patient satisfaction of their care.

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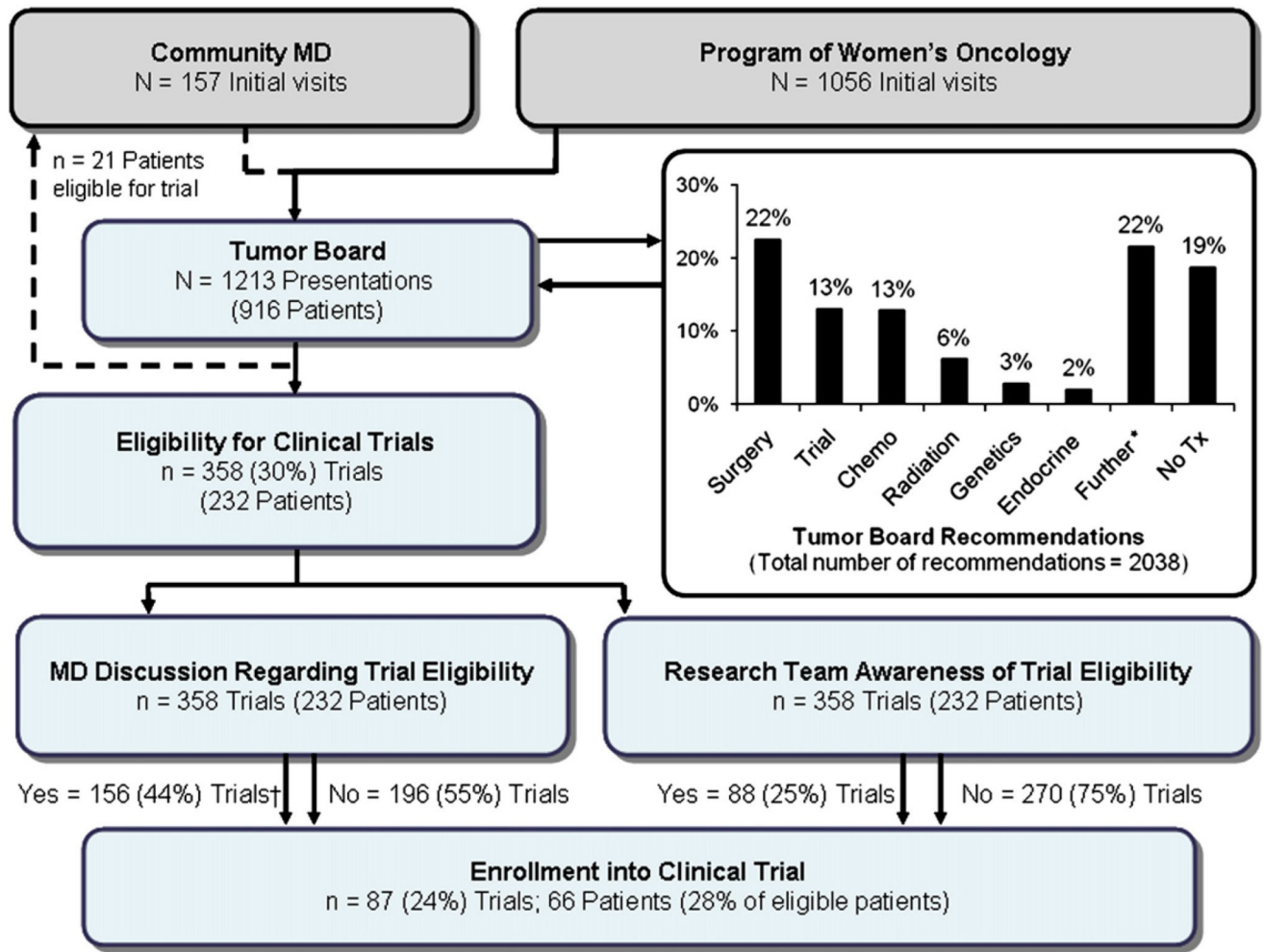


Fig. 1. Flowchart of the Program of Women's Oncology multidisciplinary Gynecologic Oncology Tumor Board process at Women and Infants' Hospital. Abbreviations: MD—Physician; Trial—Eligibility for clinical trial; Chemo—Chemotherapy; Genetics—Referral to the Cancer Risk & Prevention Program; Endocrine—Hormonal/Endocrine therapy; Further—Further work-up; Tx—Treatment. *Further work-up included: imaging, biopsy, dilatation and curettage, tumor markers, specialty consultations, exam under anesthesia, unspecified, Tumor Board re-presentation, pap smear, colposcopy, cystoscopy, hysteroscopy, proctoscopy, serial beta hcg, human papillomavirus (HPV) testing, HPV vaccine, pain clinic, urinalysis, urine cytology, laparoscopy, drainage, and laser ablation. †Missing/unknown discussions (Total 6).

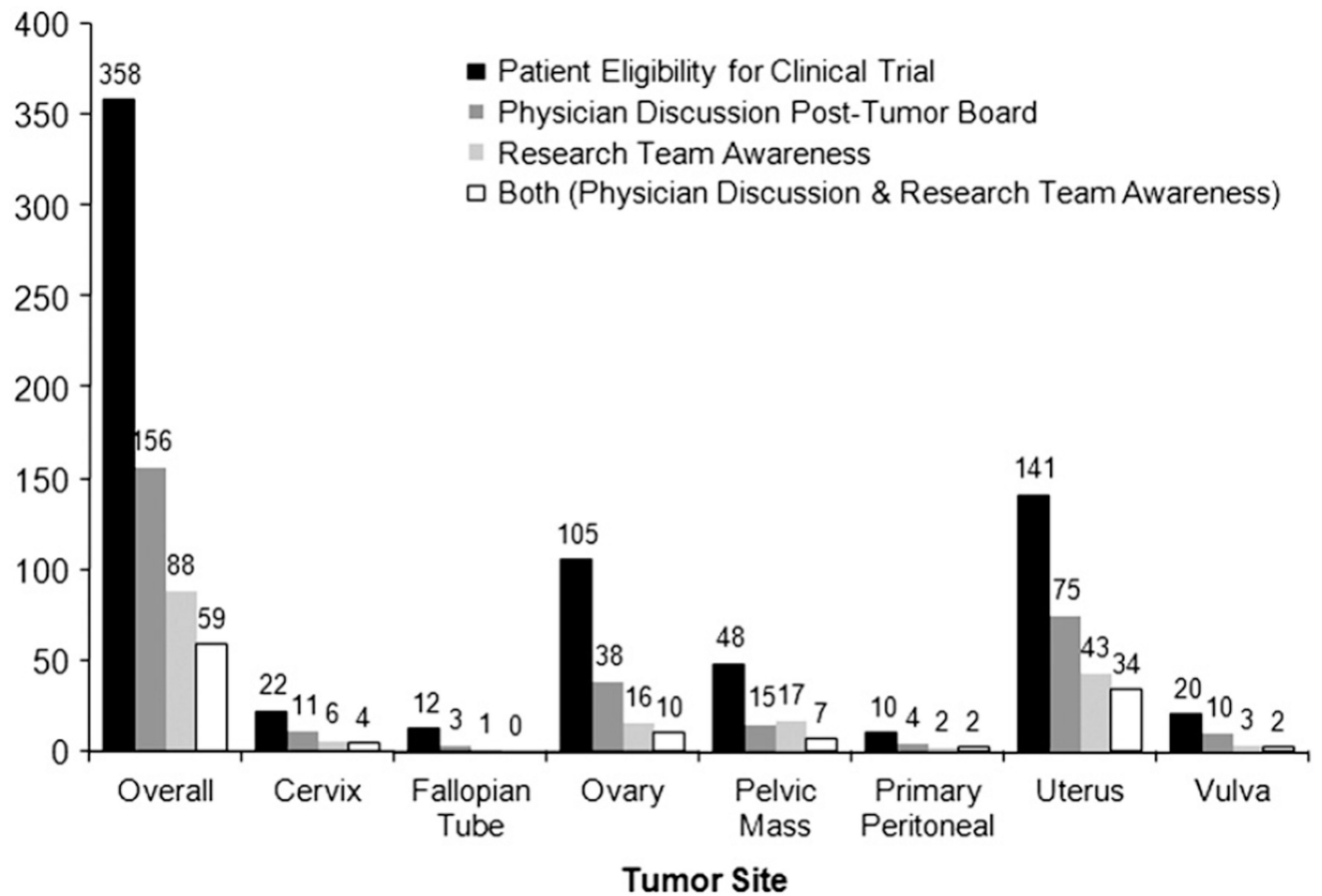


Fig. 2. Distribution of clinical trial by tumor site comparing patient eligibility, post-Tumor Board physician discussion and research team awareness of patient trial eligibility. (n/a).

Table 1

Characteristics of case presentations that were reviewed by the Multidisciplinary Gynecologic Oncology Tumor Board between March 18, 2008 and December 30, 2008.

Characteristics	<i>N</i> (%)
Age ^a	
16–34	87 (9)
35–49	193 (21)
50–64	336 (37)
65	302 (33)
Race ^{a,b}	
White	785 (90)
African American	22 (3)
Asian	11 (1)
Unspecified/other	52 (6)
Referrals to Tumor Board	1213
Program of Women's Oncology	1042 (86)
Community physician	171 (14)
Tumor Board presentations	1213
1	794 (66)
2	365 (30)
3	54 (4)

^aData based on information provided by each patient reviewed, not per case presentation, as one patient may be presented multiple times.

^bMissing data.

Table 2

Diagnosis by organ site per Tumor Board presentation.

Diagnosis/stage ^a	N = 1290; n (%)	Diagnosis/stage ^a	N = 1290; n (%)
Cervix	197 (15)	Uterus	504 (40)
Benign	3	Benign	46
LGSIL/HGSIL	5/5	CAH	10
ASCUS/AGUS	12/6	I	145
Dysplasia	31	II	19
In situ	31	III	42
I	56	IV	16
II	13	Incompletely Staged	40
III	12	Unstaged	186
IV	9	Vagina	16 (1)
Melanoma	2	Benign	1
Unstaged	12	Dysplasia	7
Fallopian tube	22 (2)	II	1
I	9	Melanoma	1
III	4	Unstaged	6
Incompletely staged	2	Vulva	90 (7)
Unstaged	7	Benign	4
GTD	7 (1)	Dysplasia	15
Partial mole	3	In situ	3
Complete mole	1	I	13
Choriocarcinoma		II	7
Stage 3	1	III	3
Unstaged	2	IV	3
Ovary	294 (23)	Incompletely staged	12
Benign	65	Unstaged	17
I	42	Paget's disease	3
II	12	Basal cell carcinoma	9
III	54	Melanoma	1
IV	10	Other	138 (11)
Incompletely staged	7	Solid tumors	31
Unstaged	104	Unknown pelvic mass	62
Primary Peritoneal	22 (2)	Unknown primary	29
III	17	Benign disease	16
IV	1	Total malignant disease	612 (47)
Unstaged	4		

Abbreviations: GTD-Gestational trophoblastic disease; CAH- complex atypical hyperplasia.

^aFIGO system as defined by the International Federation of Gynecology and Obstetrics.

Table 3

Summary of tumor board recommendations.

Recommendations	Tumor Board presentations, <i>N</i> (%)
Surgery	458 (22)
Chemotherapy	260 (13)
Radiation therapy	129 (6)
Endocrine treatment	39 (2)
Eligibility for clinical trial(s) ^a	270 (13)
Cancer Risk & Prevention Program	56 (3)
Further work up	446 (22)
Imaging	150 (7)
Biopsy	63 (3)
Dilatation and curettage	35 (2)
Tumor markers	53 (3)
Specialty consultations	76 (4)
Other ^b	69 (3)
No treatment	380 (19)
Total	2038

^a*N* represents the sum of tumor board letters that stated patient eligibility for clinical trial, regardless of the number of trials recommended.

^bOther: exam under anesthesia (12), unspecified (10), tumor board re-presentation (9), pap smear (7), colposcopy (6), cystoscopy (5), hysteroscopy (4), proctoscopy (3), serial beta hcg (2), HPV testing (2), HPV vaccine (2), pain clinic (2), urinalysis (1), urine cytology (1), laparoscopy (1), drainage (1), and laser ablation (1).

Distribution of clinical trials by cancer site comparing post-Tumor Board physician discussion and research team awareness of patient trial eligibility.

Table 4

Cancer site	Trial(s)	Eligible total N	MD, n (%)	Research, n (%)	Both, n (%)	p-value ^a	Difference ^b (95% CI)
Cervix	4	22	11 (50)	6 (27)	4 (18)	0.2	23% (-7 to 52%)
Diagnostic	3	8	2 (25)	2 (25)	1 (13)		
Therapeutic	2	14	9 (64)	4 (29)	3 (21)		
Prognostic	-	-	-	-	-		
Ovarian	14	105	38 (36)	16 (15)	10 (26)	0.0002	21% (10–32%)
Diagnostic	3	56	13 (23)	10 (18)	5 (9)		
Therapeutic	10	45	22 (49) ^c	6 (13)	5 (11)		
Prognostic	1	4	3 (75)	0	0		
Fallopian tube	7	12	3 (25)	1 (8)	0	0.6	17% (-23 to 56%)
Diagnostic	-	-	-	-	-		
Therapeutic	5	5	3 (60)	0	0		
Prognostic	2	7	0	1 (14)	0		
Primary peritoneal	8	10	4 (40)	2 (20)	2 (20)	0.5	20% (-15% to 55%)
Diagnostic	-	-	-	-	-		
Therapeutic	7	10	4 (40)*	2 (20)	2 (20)		
Prognostic	1	0	0	0	0		
Uterus	6	141	75 (53)	43 (30)	34 (24)	0.0001	28% (19–36%)
Diagnostic	4	113	54 (48)	37 (33)	29 (26)		
Therapeutic	2	28	21 (75)	6 (21)	5 (18)		
Prognostic	-	-	-	-	-		
Vulva	4	20	10 (50)	3 (15)	2 (10)	0.04	35% (5–65%)
Diagnostic	2	8	3 (38)	0	0		
Therapeutic	2	12	7 (58)	3 (25)	2 (17)		
Prognostic	-	-	-	-	-		
Solid tumor/pelvic mass	4	48	15 (31)	17 (35)	7 (15)	0.8	-4% (-24% to 15%)
Diagnostic	3	46	15 (33)*	17 (37)	7 (15)		
Therapeutic	-	-	-	-	-		
Prognostic	1	2	0*	0	0		

Cancer site	Trial(s)	Eligible total N	MD, n (%)	Research, n (%)	Both, n (%)	p-value ^a	Difference ^b (95% CI)
Total	48	358	156 (44)	88 (25)	59 (16)	<0.0001	19% (13–25%)

Abbreviations: Eligible—number of potential trial enrollments from Tumor Board recommendations; MD—post-Tumor Board discussion with physician; Research—Research team awareness; Both—Patient who received both physician discussion and were also known to the research team.

^a p-value by McNemar's test.

^b Difference in proportion of total MD discussed vs. research team aware (95% CI).

^c Missing/unknown data (total 6).