Ann Surg Oncol (2019) 26:4364–4371
https://doi.org/10.1245/s10434-019-07807-9

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – BREAST ONCOLOGY

Challenges in Clinical Trial Implementation: Results from a Survey of the National Accreditation Program of Breast Centers (NAPBC)

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ABSTRACT

Background. Although the results of clinical trials often guide best practices, changing clinical practice based on clinical trial results can be challenging. The objective of this study was to examine provider-reported barriers to adopting best clinical practices according to clinical trial data.

Methods. A cross-sectional survey was conducted of providers from the National Accreditation Program for Breast Centers about barriers that prevent the incorporation of trial findings. Descriptive analyses and multivariable analyses were performed to determine provider characteristics that were significantly associated with reported barriers.

Results. Overall, 383 institutions participated (63.5% response rate), with a total of 1226 physicians responding to the survey (80% response rate). Providers identified national guidelines and meetings as the most compelling way to receive practice-changing information. They reported the following internal barriers to trial implementation: patient preference (45%), strongly held beliefs by partners/colleagues (37%), and insufficient time to discuss new practices (30%). External barriers preventing trial implementation included a lack of agreement from multidisciplinary tumor boards (32%), fear of reimbursement loss (23%), and resistance from clinical staff (20%). Reported barriers differed by provider specialty, with plastic surgeons and radiation oncologists reporting that strongly held beliefs by partners/colleagues and disagreement from multidisciplinary tumor boards were the most significant factors preventing clinical trial implementation.

Conclusions. Physician beliefs and patient preferences are the most frequently reported barriers to clinical trial implementation. Tactics to better educate providers about how to explain new clinical trial data to their patients and colleagues are needed.

Prior Presentation This work was presented as an oral presentation at the Society of Surgical Oncology Annual Cancer Symposium, San Diego, CA, USA, 27–30 March 2019.

Electronic supplementary material The online version of this article (https://doi.org/10.1245/s10434-019-07807-9) contains supplementary material, which is available to authorized users.

First Received: 11 April 2019;
Published Online: 17 October 2019

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Although clinical trial results often denote new best practices, changing clinical practice can be challenging.[1,2] It is estimated only 14% of original research designed to improve patient care actually reaches the intended population. Furthermore, it can take that research up to two decades to accomplish widespread implementation.[3] This delay is particularly pertinent to groups such as the Alliance for Clinical Trials in Oncology (Alliance), which invests extensive resources designing and executing clinical trials.[4] The Alliance, and similar multi-institutional collaborative clinical trial groups, put forth significant contributions to improve patient care, yet their trials may not be impacting patients in a timely and effective manner. The American College of Surgeons Clinical Research Program (ACS CRP), a part of the Alliance and formerly the American College of Surgeons Oncology Group (ACOSOG), is trying to improve education to its membership via dissemination and implementation (D&I) of clinical trial data and research in mechanisms to decrease the knowledge gap.

Dissemination involves packaging clinical evidence and tailored communication to target audiences, and implementation uses uptake and adoption interventions to integrate and sustain new best-practice findings into standard care.[5] While clinical effectiveness research focuses on the effect of interventions or exposures on patient outcomes, D&I research focuses on how those effectiveness research results are enacted in practice; for example, how institutions roll out quality improvement programs,[6] or how multidisciplinary teams implement cancer clinical trial results.[7–9] While powerful, such research methods are underutilized in oncology and could be used to examine factors that may affect successful clinical practice change.

The aims of this study were to survey how providers obtain practice-changing information, identify clinical trial education resources used by physicians, examine provider-reported barriers to changing clinical practice based on new clinical trial data, and investigate whether differences exist by provider characteristics. We hypothesized that strongly held beliefs by colleagues may be the most significant barrier to clinical trial result implementation. Ultimately, this study may identify ways to optimize dissemination of results from cancer clinical trials, and decrease barriers to implement those results, so patients can receive the most up-to-date care.

METHODS

Survey Development

The ACS CRP, a division of the ACS Cancer Programs,[10] encourages collaboration and increases surgeon involvement in the Alliance.[4] The ACS CRP interdisciplinary D&I committee is comprised of academic and community surgeons and implementation scientists; the committee is tasked with finding ways to disseminate clinical trial results and offering support to cancer centers and providers to implement new clinical trial findings. The D&I committee developed a 10-question survey addressing demographics, how providers obtain clinical trial information, and internal and external barriers to clinical trial implementation. The questionnaire was revised based on cognitive interviews with five D&I members then piloted in the ACS membership survey to ensure feasibility.

Study Population and Survey Dissemination

This cross-sectional study was included within a larger survey covering multiple topics sent to physicians at breast centers accredited by the National Accreditation Program for Breast Cancer (NAPBC; another division of ACS Cancer Programs dedicated to improving quality in breast cancer care). Institutions were given credit for one of two NAPBC-required annual quality projects for participating. Surveys were distributed by mail on 23 August 2017 to the contact physician for each of the 603 NAPBC-accredited institutions. Each site was asked to have four providers complete the survey: a medical oncologist, a radiation oncologist, a plastic or reconstructive surgeon, and a breast or oncologic surgeon. Reminder phone calls to the designated contact were made 1 week after the mailing. Six weeks later (5 December 2017), a web-based survey was sent to institutions that had not responded or were missing any of the four providers. Sites were excluded if they provided less than three surveys, or if they had duplicate physician types.

Survey Items

Respondents could answer one or more of the following as the most compelling way to obtain practice-changing information: national meetings, journal articles, national guidelines, online videos/streaming from any source, local tumor board, email blasts from national specialty organizations, email blasts from journals, UpToDate (a subscription online resource for physicians), and social media such as Twitter and Facebook. Participants were asked to identify their clinical trial education resources, including paid time off for continuing medical education (CME) events or activities; unlimited or limited funds for travel to meetings; and journal subscriptions, textbooks, webinars, or other educational materials.

Next, participants were asked about internal and external barriers to clinical trial result implementation. The internal barriers listed were fear of legal repercussions,

strongly held beliefs by colleagues, lack of access to new trial information, difficulty interpreting results, added time to discuss new practices with patients, patient preferences, and outdated trial findings (ranked as large, medium, small, or not a barrier). The external barriers listed were lack of agreement at multidisciplinary tumor board, risk of losing referrals, fear of loss of reimbursement, resistance from clinical staff, and possible reprimand from institutional quality committee (ranked as always, frequently, sometimes, rarely, or never) (electronic supplementary Table 1). The survey was voluntary, such that respondents could skip questions if desired.

Practice and Provider Factors

Physicians self-reported their medical specialty (medical oncologist, radiation oncologist, plastic or reconstructive surgeon, and breast or oncologic surgeon), sex (male, female), experience (defined by years in practice, i.e. < 5, 5–9, 10–15, 16–20, and > 20), and volume (defined by patient visits per week, i.e. < 10, 10–29, 30–49, > 50). Hospital characteristics collected from the NAPBC included region (Northeast, Midwest, South, West), practice type (free-standing, free-standing with hospital affiliation, group practice, or hospital-based), hospital size (0–200 beds, 201–500 beds, > 500 beds), and medical school affiliation.

Data Analysis

Participant demographics, facility characteristics, and survey answers were summarized using descriptive statistics. Internal barriers reported as 'large barrier' or 'medium barrier' were collapsed as 'yes' and compared with responses of 'small barrier' or 'not a barrier' collapsed as 'no'. Likewise, external barriers reported as 'always', 'frequently', or 'sometimes' were collapsed as 'yes' and compared with responses of 'rarely' or 'never' collapsed as 'no'. Chi square tests were used to examine reported resources and barriers to practice change. A multivariable analysis adjusting for provider specialty, age, sex, volume, practice region, and years in practice was performed for the three most often reported internal barriers (strongly held beliefs by colleagues, added time to discuss new practices with patients, patient preferences) and external barriers (lack of agreement at multidisciplinary tumor board, fear of loss of reimbursement, resistance from clinical staff) to determine independent factors associated with reported barriers. Due to the voluntary nature of the survey, missing responses varied by each question. Due to significant missing data (defined as $> 50\%$ missing), practice type and hospital size were not included in the multivariable analysis. A p value < 0.05 was considered significant. All statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC, USA). The University of California San Diego Institutional Review Board approved the study for human subject research (IRB #170293).

RESULTS

Provider and Hospital Characteristics

Of 603 NAPBC institutions, 383 responded, a site participation rate of 63.5%. Each institution was asked to return four surveys, totaling 1532 possible surveys from 383 institutions; 1226 were returned, representing an 80% response rate for individuals from participating institutions. Providers were well-distributed across the four specialties: medical oncology (24%), radiation oncology (26%), plastic surgery (20%), and breast surgery (27%). Approximately one-third of providers reported being in practice > 20 years ($n = 398$, 32%), and 445 (36.0%) reported a patient volume of 10–29 breast cancer patients per week. Approximately half of the respondents were male ($n = 639$, 52%). The most frequent institution characteristics were hospital-based practice (30%), Midwest and South region (32% each), 0- to 200-bed hospital size (22%), and non-medical school affiliated (88%) (Table 1).

Resources for Practice Change

Of the ways listed to obtain clinical trial information, 468 (40%) selected national guidelines as the most compelling, and 379 (33%) selected national meetings (Fig. 1). Only 1% of physicians ranked social media as the top way to obtain trial information. Regarding clinical trial education resources, 788 (64%) reported paid time off for CME, 31 (2.5%) reported unlimited funds for travel/meetings, 860 (70%) reported limited funds, and 724 (59%) reported access to journal subscriptions supported by their employer/institution.

Barriers to Clinical Trial Implementation

Patient preferences were the most frequently reported internal barriers to clinical trial implementation (reported by 45%), followed by strongly held beliefs by partners/colleagues (37%), added time to discuss new practices (30%), and lack of access to new trial information (25%). Fear of legal repercussions, outdated trial findings, and difficulty interpreting published results were each reported as significant internal barriers by fewer than 20% of respondents (Table 2). Lack of agreement from the multidisciplinary tumor board was the most frequently reported external barrier (reported by 32%), followed by fear of

TABLE 1 Provider and hospital characteristics

	N	%
Provider characteristics (*N* = 1226)		
Specialty		
Medical oncologist	300	24.47
Radiation oncologist	316	25.77
Plastic or reconstructive surgeon	248	20.23
Breast or oncologic surgeon	322	26.26
Other	9	0.73
Not answered	31	2.53
Experience (years)		
< 5	168	13.70
5–9	212	17.29
10–15	236	19.25
16–20	166	13.54
> 20	398	32.46
Not answered	46	3.75
Volume (patients/week)		
< 10	326	26.59
10–29	445	36.30
30–49	207	16.88
> 50	205	16.72
Not answered	43	3.51
Sex		
Male	639	52.12
Female	543	44.29
Other	3	0.24
Not answered	41	3.34
Hospital characteristics (*N* = 383)		
Practice type		
Free-standing	5	1.31
Free-standing with hospital affiliation	26	6.79
Group practice	6	1.57
Hospital-based	114	29.77
Other	2	0.52
Not answered	230	60.05
Region		
Northeast	87	22.7
Midwest	121	31.59
South	122	31.85
West	51	13.32
International	1	0.26
Not answered	1	0.26
Hospital size (number of beds)		
0–200	85	22.19
201–500	67	17.49
> 500	29	7.57
Not answered	202	52.74
Medical school affiliation		
Yes	46	12.01
No	336	87.73
Not answered	1	0.26

TABLE 2 Provider opinions on whether they feel internal barriers to clinical trial result implementation

Barrier	*N*	%
Fear of legal repercussions for changing practice patterns		
Yes	221	18
No	946	77
Not answered	59	5
Strongly held beliefs by your partners/colleagues		
Yes	451	37
No	715	58
Not answered	60	5
Lack of access to new trial information		
Yes	301	25
No	864	70
Not answered	61	5
Difficulty interpreting published results		
Yes	195	16
No	968	79
Not answered	63	5
Added time to discuss new practices with patients		
Yes	364	30
No	797	65
Not answered	65	5
Patient preferences		
Yes	551	45
No	613	50
Not answered	62	5
Trial findings are outdated		
Yes	226	18
No	922	76
Not answered	78	6

reimbursement loss (23%), and resistance from clinical staff (20%). Risk of losing referrals and reprimand from the Institutional Quality Committee were reported as external barriers by fewer than 20% of respondents (Table 3).

Survey Responses by Provider Characteristics

Compared with other professions, plastic surgeons reported less paid time off for CME and fewer travel funds

TABLE 3 Provider opinions on whether they feel external barriers to clinical trial result implementation

Barrier	*N*	%
Lack of agreement from your multidisciplinary tumor board		
Yes	390	32
No	804	65
Not answered	32	3
Risk of losing patients from your referring doctors		
Yes	230	19
No	965	79
Not answered	31	2
Fear of loss of reimbursement from payors, either government or private		
Yes	282	23
No	896	73
Not answered	48	4
Resistance from clinical staff		
Yes	240	20
No	951	77
Not answered	35	3
Possible reprimand from institutional quality committee		
Yes	126	10
No	1063	87
Not answered	37	3

(both $p < 0.01$). Female respondents described more paid time off for CME ($p < 0.01$), more travel funds ($p < 0.01$), and more journal subscriptions than men ($p = 0.02$). Less experienced providers (< 5 years in practice) reported more paid time off for CME and more travel funds (both $p < 0.01$), whereas higher-volume providers described more paid time off for CME ($p = 0.01$) and more travel funds ($p \leq 0.01$). Providers practicing with medical school affiliations also described more funds for travel than those at non-affiliated institutions ($p = 0.04$).

There were no significant differences in reported barriers by any hospital characteristic (practice type, hospital size, or medical school affiliation), but there were differences by provider characteristics, some of which persisted on multivariable analysis. Radiation oncologists and plastic surgeons more often reported strongly held beliefs by partners/colleagues as internal barriers to clinical trial result implementation (both $p < 0.01$). Additionally, plastic surgeons more often reported that patient preferences were a significant internal barrier ($p = 0.02$). Compared with medical oncologists, radiation oncologists, plastic surgeons, and surgical oncologists more frequently reported a lack of agreement from the multidisciplinary tumor board as an external barrier preventing clinical trial result implementation ($p < 0.01$, 0.03, and < 0.01, respectively); plastic surgeons and surgical oncologists reported fear of loss of reimbursement more often than medical oncologists ($p = 0.02$ and $p < 0.01$, respectively); and all provider specialties reported resistance from clinical staff as an external barrier more frequently than medical oncologists (all $p < 0.01$). Providers with > 20 years of experience were less impacted by partners/colleagues' beliefs and lack of agreement from the multidisciplinary tumor board. Sex, volume, and practice region did not affect the reported barriers (Table 4).

DISCUSSION

In this study, providers from NAPBC-accredited institutions identified national guidelines as the most compelling way to obtain practice-changing information. Patient preferences were the most frequently reported internal barrier, and lack of agreement from the multidisciplinary tumor board was the most significant external barrier to clinical trial result implementation. There were significant differences in reported barriers based on provider characteristics: surgeons and radiation oncologists more frequently reported disagreement from their multidisciplinary tumor board as a barrier, and plastic surgeons more frequently reported patient preferences as a barrier. As providers gain experience, they less frequently report barriers to clinical trial implementation.

Of the available routes to obtain practice-changing information, national guidelines provide the most robust synopsis of the literature on a topic[11] and can dramatically change practice;[12,13] however, guideline development is time-consuming and impractical to reproduce for every aspect of clinical care. For example, efforts to synthesize consensus guidelines for non-invasive and early-stage invasive breast conservation margins required collaborative efforts by experts and support from their specialty associations, including the Society of Surgical Oncology, American Society for Radiation Oncology, and American Society of Clinical Oncology.[14–16] Instead, in the current study, we identify targets for generalizable, expeditious interventions to increase clinical trial implementation.

Provider differences in reported resources and barriers may help develop targeted implementation strategies. Plastic surgeons reported less paid time off and fewer travel funds, and more often reported patient preferences as a barrier to clinical trial result implementation. Increasing access to educational resources and activities for plastic surgeons could certainly benefit the patient as new clinical trial data would enhance the multidisciplinary discussion and surgical decision. Plastic surgeons and radiation oncologists more often reported beliefs held by partners/colleagues as barriers, and all three specialties (including breast surgeons) had increased odds of reporting

TABLE 4 Multivariable analysis evaluating the effect of provider characteristics on the most frequently reported (a) internal barriers and (b) external barriers preventing implementation

Provider characteristics	Strongly held beliefs by partners/colleagues				Added time to discuss new practices with patients				Patient preferences			
	OR	95% CI		*p* value	OR	95% CI		*p* value	OR	95% CI		*p* value
(a) Independent predictors of reported internal barriers to implementing clinical trial findings in practice												
Specialty												
Medical oncologist (ref)	–	–	–	–	–	–	–	–	–	–	–	–
Radiation oncologist	2.57	1.78	3.72	< **0.01**	0.78	0.53	1.14	0.19	0.93	0.66	1.32	0.70
Plastic surgeon	3.05	2.06	4.54	< **0.01**	1.42	0.94	2.08	0.09	1.56	1.07	2.27	**0.02**
Surgical oncologist	1.26	0.88	1.82	0.21	1.13	0.80	1.62	0.50	1.05	0.75	1.46	0.79
Experience (years)												
<5 (ref)	–	–	–	–	–	–	–	–	–	–	–	–
5–9	0.67	0.43	1.04	0.07	0.88	0.56	1.38	0.56	0.79	0.52	1.21	0.29
10–15	0.67	0.44	1.04	0.07	0.92	0.59	1.43	0.71	0.87	0.57	1.33	0.52
16–20	0.84	0.53	1.33	0.45	1.01	0.63	1.63	0.97	0.84	0.53	1.32	0.45
> 20	0.51	0.34	0.76	< **0.01**	0.73	0.48	1.10	0.13	0.74	0.50	1.09	0.13

Provider characteristics	Lack of agreement from multidisciplinary tumor board				Fear loss of reimbursement from payors, either government or private				Resistance from clinical staff			
	OR	95% CI		*p* value	OR	95% CI		*p* value	OR	95% CI		*p* value
(b) Independent predictors of reported external barriers to implementing clinical trial findings in practice												
Specialty												
Medical oncologist (ref)	–	–	–	–	–	–	–	–	–	–	–	–
Radiation oncologist	1.91	1.31	2.80	< **0.01**	0.92	0.62	1.37	0.69	2.18	1.34	3.52	< **0.01**
Plastic surgeon	1.59	1.05	2.41	**0.03**	1.61	1.06	2.44	**0.02**	3.06	1.86	5.03	< **0.01**
Surgical oncologist	1.79	1.24	2.59	< **0.01**	0.51	0.34	0.77	< **0.01**	1.90	1.19	3.03	< **0.01**
Experience (years)												
<5 (ref)	–	–	–	–	–	–	–	–	–	–	–	–
5–9	0.68	0.43	1.06	0.09	1.20	0.73	1.97	0.48	0.83	0.49	1.40	0.48
10–15	0.83	0.53	1.28	0.39	1.07	0.65	1.77	0.79	1.04	0.63	1.74	0.87
16–20	0.96	0.61	1.53	0.87	1.60	0.95	2.68	0.08	1.11	0.65	1.90	0.70
> 20	0.55	0.37	0.82	< **0.01**	1.10	0.69	1.75	0.69	0.68	0.42	1.11	0.12

Values in bold are statistically significant

OR odds ratio, *CI* confidence interval

Additionally, controlled for provider volume, provider sex, and region; the ORs for these factors are not shown because they were not significant for any barrier

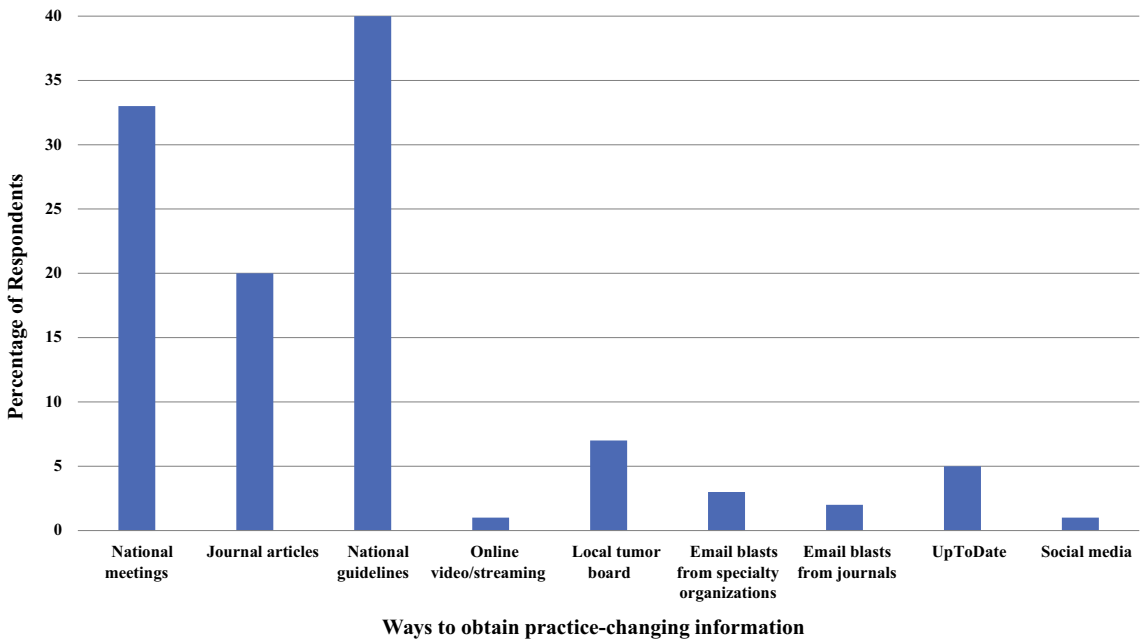

FIG. 1 The most compelling ways to receive practice-changing information, identified by survey respondents. This figure represents the most common ways that survey respondents obtain practice-changing information. The top response was national guidelines at 40%, followed by national meetings at 33%, and journal articles at 20%. All other modes of information transfer were rated < 10% of the time. *Respondents can supply more than one answer, therefore percentages add to more than 100%

lack of agreement from the multidisciplinary tumor board, and resistance from clinical staff, as barriers to clinical trial implementation compared with medical oncologists. Prior studies have reported that interprofessional tensions and communication are the most powerful mediators of practice change.[17,18] Involving members not typically included in the multidisciplinary tumor board discussions could reduce resistance from clinical staff, reduce discrepancies in awareness and uptake of data-driven clinical practices, and provide more cohesive recommendations in clinical care. Furthermore, a standardized and objective framework for tumor board discussions could limit subjective interactions and promote pertinent discussions for implementing clinical trial data. The D&I Committee is developing such a tool, which includes an educational video and accompanying study guide to help interpret and implement an Alliance clinical trial; the video discusses a breast cancer trial and is currently being pilot tested in Commission on Cancer-accredited hospitals.

Although this is one of the first studies to examine barriers to clinical trial implementation, there are some limitations. First, selection bias exists; the survey was administered to NAPBC-accredited providers who may be more knowledgeable about ongoing trials, even actively enrolling, thus making concerted efforts to incorporate trial data into patient care.[19] Second, some of the results may not be applicable across disease sites. Breast cancer providers may feel the impact of patient preference because multiple treatment options result in equivalent oncologic outcomes allowing patient choice, whereas pancreatic cancer providers, for example, where a pancreaticoduodenectomy may be the only option, may not be subject to these pressures.

No differences were reported by hospital characteristics, but respondents were not asked to self-identify as academic or community-based and this represents a limitation of the current work. This omission was deliberate because the ACS CRP and Alliance rely equally on their community and academic members, but clinical trial result incorporation may differ based on practice setting. Prior studies have noted that the dissemination of new best-practice results is most challenging in the community-setting;[20] however, 85% of cancer care is performed at community-based practices.[21] This imbalance between access to educational resources and distribution of patient care presents a predicament. Thus, community-based practices may be an ideal target for the D&I Committee to improve clinical trial dissemination. Optimally, improved utilization of pre-existing mechanisms for information transfer such as the National Comprehensive Cancer Network platform, or newer strategies such as the ACS CRP multidisciplinary tumor board video presentation tool, can improve access to clinical trial data for community practices.

Lastly, the central hypothesis was disproven; we were surprised to find that patient preferences were reported as the most significant barrier to clinical trial implementation

and unfortunately this barrier may be the most difficult to address. The D&I and Education Committees of the ACS CRP are developing patient education videos aimed at boosting clinical trial enrollment, but, according to the findings of this study, alternative strategies need to be developed to educate patients about practice-changing results. If this first attempt at a patient education video is successful, further patient-facing interventions will be developed by these committees to increase patient awareness of clinical trial results. One such intervention will include a survey designed to solicit factors that patients identify as barriers to implementing clinical trial results in their care.

CONCLUSIONS

Providers can critically influence efforts to promptly implement new best practices according to clinical trial results. It is therefore important to understand how providers obtain practice-changing information and the barriers they perceive to implementing these changes. Despite the limitations of our study, it provides important preliminary data suggesting that perceived barriers vary by provider characteristics, which can help ongoing national efforts tailor interventions to increase clinical trial implementation and reduce the time needed for patients to realize these results.

DISCLOSURES Nicole Lopez reports a fellowship grant from the National Library of Medicine (Grant No. 5T15LM011271-07). Kelly Hunt reports institutional research funding from Lumicell and Endomag, and medical advisory board roles at Armada Health and Merck & Co. Anna Weiss, Erin P. Ward, Katherine C. Lee, Abigail S. Caudle, Diana Dickson-Witmer, Cecilia Chang, Kaitlyn Kelly, Linda Williams Martin, Lisa Kay Jacobs, Katherine Yao, and Sarah L. Blair have nothing to disclose.

FUNDING This work was supported by the ACS CRP and a donation from the Chicago Platform Tennis Charities.

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