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Challenges and Facilitators of Community Clinical Oncology Program Participation: A Qualitative Study

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EXECUTIVE SUMMARY

Successful participation in the National Cancer Institute's (NCI) Community Clinical Oncology Program (CCOP) can expand access to clinical trials and promote cancer treatment innovations for patients and communities otherwise removed from major cancer centers. Yet CCOP participation involves administrative, financial, and organizational challenges that can impact hospital and provider participants. This study was designed to improve our understanding of challenges associated with CCOP participation from the perspectives of involved providers, and to learn about opportunities to overcome these challenges.

We conducted five case studies of hospitals and providers engaged with the CCOP. Across organizations we interviewed forty-one administrative, physician, and nurse key informants. We asked about CCOP participation, focusing on issues related to implementation, operations, and organizational support. We analyzed interview transcripts both deductively and inductively, exploring themes that emerged.

Interviewees noted seven challenges associated with CCOP participation: 1) lack of appreciation for the value of participation; 2) poor understanding about CCOP operations; 3) cost; 4) need to meet CCOP requirements; 5) required workflow changes; 6) managing patient recruitment and physician involvement; and 7) sustaining hospital leadership support. Informants also suggested three major opportunities to facilitate participation: 1) increase awareness of the CCOP; 2) enhance commitment to the CCOP; and 3) promote and support champions of the CCOP.

Improving our understanding of the challenges and facilitators of CCOP participation may help hospitals and providers in efforts to increase and sustain participation in the CCOP, thus helping to helping to preserve access to innovative medical treatment options for patients in need.

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Keywords

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BACKGROUND

As the potential increases for scientific advances to improve the delivery of cancer care, health services providers are challenged to translate research findings into practice. The National Institutes of Health's (NIH) Roadmap initiative was established to facilitate this translation process (Zerhouni 2003; NIH 2011), including supporting the development of provider-based research networks (PBRNs) that can promote the extension of clinical trials research into community practice settings (Westfall, Mold and Fagnan 2007; Ryan, Berrebi, Becket, Taylor, Quite, Cho, et al. 2011).

The Community Clinical Oncology Program (CCOP) of the National Cancer Institute (NCI) is an example of a PBRN—a collaborative partnership between research institutions and community-based physicians and medical groups—that has shown early promise in accelerating cancer treatment progress (Lanier 2008; NCI 2011; Minasian, Carpenter, Weiner, Anderson, McCaskill-Stevens, Nelson, et al. 2010). The NCI CCOP was initiated in 1983 specifically to facilitate Phase III clinical trials involving cancer prevention, treatment, and control in community-based practice settings. By 2010, the NCI's total budget for the CCOP was $93.6 million, and provided support for 47 CCOP organizations nationwide. There are currently 340 hospitals and 2,900 community physicians (e.g., oncologists, surgeons) represented in the NCI CCOP (NCI 2011b).

The NCI's CCOP is designed to disseminate and implement advances in cancer care through support of a research infrastructure linking cancer investigators and academic centers to community-based settings where the majority of patients receive their care (Minasian, et al. 2010; NCI 2011). Successful CCOP organizations thus expand access to clinical trials and promote cancer treatment innovations within patient populations and communities that might not otherwise have such access (Minasian et al. 2010; Sales, Smith, Curran, and Kochevar 2006).

In practice, individual CCOP organizations apply for and receive research grant funding through an NCI-led peer review process. Grant awards depend upon patient recruitment to clinical trials and research productivity, but do not typically cover all costs associated with maintaining the clinical trials research infrastructure (Minasian et al. 2010; Reiter, Song, Good, Minasian, Weiner, and McAlearney 2011). As a result, CCOP participation involves issues of organization, cost, and planning that may be of concern to both hospitals and provider participants. In addition, concerns such as building relationships with physicians, monitoring data collection, and recruiting qualified staff have been specifically noted (Lamb, Greenlick and McCarty 1998; McKinney, Weiner and Wang 2006; Weiner, McKinney and Carpenter 2006). Unfavorable economic climates can thus create pressures for hospitals attempting to sustain CCOP participation (Carpenter, Weiner, Kaluzny, Domino, and Lee 2006; McKinney, Weiner, and Carpenter 2006; Sung, Crowley, Genel, et al. 2003).

Although prior studies have examined these issues from the perspectives of policymakers and clinical scientists, we know very little about CCOP participation challenges from the perspectives of the hospitals and clinicians who participate in the CCOP, and even less about facilitators of participation. Further, for those hospitals interested in CCOP participation,

little information is available to inform their planning and decision-making processes regarding the CCOP.

As part of a larger study examining the business case for CCOP participation, we undertook the additional analyses reported in this paper to improve our understanding of the challenges hospitals and clinicians associate with CCOP participation. We were also interested in learning about opportunities to overcome participation challenges that could provide insight to hospitals and other provider organizations struggling to sustain CCOP involvement.

METHODS

We designed a case-based qualitative study (Yin 2008) to examine hospitals' and clinicians' perspectives about the business case for CCOP participation, including examining considerations of the financial and non-financial benefits associated with participation (reported elsewhere). From this larger study, interviewees' responses to direct questions about participation benefits frequently included perspectives about the overall challenges and facilitators of CCOP participation. We undertook secondary analyses of this extensive qualitative data set to learn more about these participation challenges from the perspectives of the multiple key informants we interviewed, as we further describe below.

Study Setting and Sample

We purposively selected CCOP organizations for our study in order to ensure that our sample varied with respect to CCOP organization size, structure, geographic region, and maturity (i.e., length of operations as a CCOP). We were interested in these dimensions in order to address our research questions about the challenges and facilitators of CCOP participation from the perspectives of different types of CCOP organizations, and from interviewees who had differing lengths of experience with the NCI CCOP.

Our final study sample included four established CCOP provider organizations, two of which had been in operation for over 10 years, and two of which had been in operation for fewer than 10 years, and one hospital that had recently applied to become a CCOP organization but had not yet been selected. By interviewing multiple key informants across these five organizations, we were able to ensure that we reached saturation with respect to interviewees' responses to the questions we asked; this strengthens the results of our study, despite the sample size of five organizations.

Data Collection

Across the five study sites, we conducted 41 key informant interviews via telephone between August 2008 and April 2010. For each site, we identified a key contact person associated with the CCOP (e.g., the CCOP administrator or CCOP principal investigator), and then asked that individual to identify additional key informants appropriate for our study. We sought to interview both administrators and clinicians associated with the CCOP provider organizations, including community-based physicians who had been involved in CCOP clinical trials research.

Key informants included administrative representatives (n=22) (e.g., administrators and staff members involved in CCOP operations), physicians (n=13), and nurses (n=6). We present additional detail about our key informants by site and informant type in Table 1. Sites are labeled A–E to maintain confidentiality. Informed consent was obtained from all interviewees.

We used a standardized guide to facilitate the interview process, with one version tailored for administrative informants and another tailored for clinical informants. The interview

guides included both semi-structured questions and probes designed to permit deeper exploration of informants' responses. Questions about CCOP participation were asked directly of all informants and included the following five general domains: 1) history and background; 2) CCOP participation; 3) direct financial costs and benefits of CCOP participation; 4) non-financial (i.e., incidental) costs and benefits of CCOP participation; and 5) return on investment. Questions in domain 3 (e.g., "What are the direct costs associated with CCOP participation?" and "Are there additional costs as well?"), and domain 4 (e.g., "Are there non-financial costs associated with CCOP participation?" and "Have you experienced any difficulty hiring or retaining qualified research staff?") often stimulated responses that involved interviewees discussing the challenges of CCOP participation.

Throughout the course of the study, we reviewed our interview progress and interview transcripts to ensure that our results were both valid and comprehensive across the study sites. In cases where respondents' answers prompted new question probes during a given interview, we used that opportunity to enhance our interview guide for future interviews. For instance, our post-interview discussions about two informants' answers to questions about the costs of providing clinical trials led us to explore the topic of patients' insurance coverage by including a specific question probe in subsequent interviews. Similarly, our open-ended approach to concluding our interviews led several interviewees to speculate about what could help their organizations with respect to CCOP participation; we then decided to formally include a concluding question about facilitators of CCOP participation in future interviews.

Key informant interviews lasted 30–60 minutes, with the majority conducted by at least two interviewers. Each interview was recorded and transcribed verbatim, then transcripts were verified and corrected by the study investigators to permit further analyses.

Analyses

We analyzed interview data using a combination of deductive and inductive methods (Miles and Huberman 1994; Strauss and Corbin 1998). Using a grounded theory approach (Strauss and Corbin 1998; Glaser and Strauss 1967), we reviewed interview notes and transcripts, and held discussions about preliminary findings as the study progressed. These discussions enabled us to identify themes that were emerging from our interviews, and prompted the development of formal question probes to include in subsequent interviews, as discussed above. At the conclusion of our interviews we formed an analysis team comprised of the lead qualitative investigator and two research assistants to code all of the transcripts.

For our inductive analysis process, we developed a coding book that included codes based on responses to all of the direct questions that key informants had been asked. The coding team then used this code book to code three common transcripts, then met to reach agreement about code definitions and code use. Our analyses were supported by use of the Atlas.ti qualitative data analysis software (Scientific Software Development 2009).

Our deductive analysis process was based on our iterative review of codes and transcripts that occurred as the coding process proceeded. Throughout this process, the coding team met periodically to ensure coding consistency, and to discuss the emergence of themes and sub-themes individual coders found in the data. As a group we defined themes and sub-themes when we found confirmation across at least three case sites, and we reaching agreement about their characterizations among the members of the analysis team.

The results we report in this paper include both findings that emerged from respondents' answers to questions that did not directly ask about the challenges and facilitators of CCOP participation, and from interviewees' responses to direct questions about facilitators. For

example, in response to a question about the costs of CCOP participation, an interviewee might describe the difficulty of recruiting patients and physicians to participate, or concerns about the actual costs of the trials being incurred by the organization—both factors that we classified as challenges of CCOP participation. Similarly, when asked about how the organization supports the CCOP, interviewees often described factors that we characterized as facilitators of CCOP participation. We were also able to characterize these facilitators based on answers to our direct question about what facilitates CCOP participation. We discuss our findings about these themes and sub-themes next.

RESULTS

Challenges of CCOP Participation

We categorized interviewees' comments related to the challenges of CCOP participation into seven topics that were reportedly important across the five study sites: 1) Appreciation for the Value of a CCOP; 2) Understanding about CCOP Operations; 3) Cost; 4) CCOP Requirements; 5) Workflow Changes; 6) Managing Patient Recruitment and Physician Involvement; and 7) Sustaining Hospital Leadership Support. Below we present each of these challenges individually, and we present additional verbatim responses from our informants to further characterize these challenges in Table 2.

1. Appreciation for the Value of a CCOP—Both administrative and clinical interviewees across sites noted how the lack of appreciation by senior leadership for the value of a CCOP created a major challenge for CCOP participation. As one CCOP physician principal investigator (PI) noted, "I don't think they [senior management] understand how cutting edge in terms of the research is that can be done through a CCOP." Even in the site applying for a CCOP grant, an interviewee explained, "I'm not so sure, to be honest, if the senior leadership really understands what a CCOP is or how important it might be to a cancer program." This lack of understanding and appreciation was apparently of particular note when informants expressed concern about the need to continually justify CCOP participation and sustaining CCOP involvement.

2. Understanding CCOP Operations—Interviewees across sites also commented upon the challenges associated with understanding and managing CCOP operations. This issue was raised with respect to both the initial decision to engage with the CCOP, and regarding management of CCOP participation over time. As one interviewee commented, "We were all busy, you know, flying through meetings, looking through the latest protocol [i.e., procedures associated with a clinical trial], but not talking about how do we do the nuts and bolts of our business." Another summarized, "The one thing that floored me when I walked into this was, do you understand that if you don't have a good business manager you won't go anywhere? This is not something that should be left to chance. You really need a professional to understand how you navigate the structure of the NCI and how you run a business." The need for specific understanding of CCOP operations was especially salient in the context of threatened budgets associated with maintaining CCOP involvement.

3. Cost—A third evident challenge was affording CCOP participation. One physician, in reflecting about this challenge, commented, "obviously the financial burden on the practices. …You find out that doing all this costs you money. It's a lot of burden on you and then you start wondering, why am I doing this?" Similarly, a CCOP administrator explained, "… you're working at a loss business here. You've got to sell that. You've got to find ways to support it, and you have to kind of keep that moving forward. And I don't know too many loss businesses that actually survive. So if you're going to do that, you better be a professional, because this is not something left to lightweights." Respondents were generally

aware that the CCOP organization received some support from NCI, but their comments about cost as a challenge to sustained CCOP participation were common across respondent types, and indicated a level of insecurity about sustaining CCOP participation over time.

4. Dealing with CCOP Requirements—Meeting the requirements of CCOP participation was also noted as a challenge across study sites. As one administrator noted, "I think they [NCI] present a lot of challenges in the program that they dump on the CCOPs themselves to solve. They say this is what we want you to do, you know…but sorry that there aren't any protocols for you." Another administrator explained, "some of these protocols… you actually have to have your plan approved before you can treat them. And so if you sort of get behind and say, oh this guys needs to start tomorrow, and I just saw him yesterday, there isn't enough time to do a plan and ship it to [location] to approve to get it back by tomorrow." These requirements raised concerns about the viability of maintaining CCOP participation when the burden of meeting CCOP requirements did not seem to match the perceived benefits of participation.

5. Changing Workflow to Accommodate the CCOP—A fifth challenge involved the changes in work required to accommodate CCOP participation. Informants explicitly discussed the need to make changes in employee training, data collection processes, and general operations to support participation. One nurse commented about "…the sheer number of patients that we see in the clinic, and the number of satellite offices that we've had opened. So each one of those requires training, and bringing on new nurses, and improving our quality as far as the orientation process, you know all of that." Another described how the CCOP also involved additional employee stress: "Because you really realize that we all are very stressed with caring for a population that may or may not survive. And riding that rollercoaster with them and helping them navigate is really a huge part of why we're successful. …Supporting the people I work with is huge." Additional comments described challenges around laboratory, pharmacy, finance, and institutional review board process changes, all areas that were of concern when informants were discussing both initiating and sustaining CCOP involvement.

6. Managing Recruitment and Physician Involvement—The issue of managing patient recruitment to clinical trials was also mentioned as a challenge across sites. Comments were made in the context of both recruiting sufficient numbers of patients to maintain multiple trials, and ensuring physician participation in the trials that had been opened. As one informant summarized, "We have quite a few people [physicians] who are, quote, 'on the list.' And then there's the people who are really, really active. These are the people that are kind of the bedrock 'A team', if you will, that's always front and center. .... but there are physicians who don't really participate at all." Balancing trial recruitment needs with varying levels of physician involvement and engagement appeared to challenge all CCOP study sites, and indicated another area of concern about sustaining CCOP participation.

7. Sustaining Hospital Leadership Support—The seventh challenge mentioned across sites was that of how to sustain administrative support for the CCOP over time. This issue was salient with respect to both ongoing operations and organizational decisions to re-apply for a CCOP grant. As one CCOP manager noted, "I think some of the upper level high-liners would vote that we just don't need this here anymore, it's hurting the hospital's bottom line, let's just do away with it. So, and I've heard other CCOPs around the country having some of those issues; having to go to battles to maintain themselves." Similarly, physicians expressed concern about the sustainability of support for CCOP participation over time. One explained, "It's kind of like, they just give it, they just say they support it,

but then when it comes time to say how much they're going to support it, there's always something else that is more important. So the research budget gets hacked every year." Comments from all types of informants across each of the CCOP sites suggested that the need to engage and sustain support over time was a particularly salient challenge they associated with CCOP participation.

Key Success Factors Facilitating CCOP Participation

We categories interviewees' comments about what could help support, or facilitate, CCOP participation into three main themes: 1) Awareness; 2) Commitment; and 3) Champions. These themes appeared salient across informant types and study sites (i.e., they were consistently mentioned across at least three sites), and represented perspectives about the factors related to both becoming a CCOP, and maintaining CCOP participation. Further explanation of these facilitators and the sub-themes associated with each main theme are provided next, with additional evidence from respondents' verbatim quotations presented in Table 3.

1. Awareness—The opportunity to increase awareness of the CCOP to facilitate CCOP participation was repeatedly noted across sites. This theme was characterized by two related sub-themes--building awareness and understanding of the importance of the CCOP across the organization, and keeping doctors and patients informed about clinical trials.

First, comments involving *building awareness and understanding* were common. One CCOP manager explained, "And I think some of our upper-level VPs support that and understand it and get why we're here and see the value of us." In another site an interviewee commented, "So we have gotten the message from them [hospital leadership] that they understand who we are, what we're doing and how important we are, and they support us in that role. They allow our administrator to do what we need to do to keep that going."

Second was the importance of *keeping physicians and patients informed about CCOP trials*. One site's administrator explained, "The clinical staff here have really done a good job of keeping all principal investigators informed of new trials. They have these cards that they make for each of the physicians to put in their pockets; very widely used. And every trial that's opened. And it's updated very, very frequently." This sub-theme was also apparent in informants' comments about how they needed to inform new clinicians about the CCOP. For instance, one administrator explained how they would "…bring on new doctors that are new to this research program and get them comfortable and referring to the protocols and aware of the protocols, and understanding how our intake system works." Related comments also involved descriptions of explicit organizational communication efforts.

Informants' comments about the importance of *awareness* in both generating interest in becoming a CCOP, and in sustaining CCOP participation were noteworthy because of their salience to the multiple types of key informants. CCOP-involved administrators and staff knew that maintaining awareness of the CCOP and its benefits could help ensure interest in participation, and facilitate participation by already involved physicians.

2. Commitment—The importance of a commitment to CCOP participation was also emphasized across sites, and was distinguished as either commitment from hospital administration, or from clinicians. First, *commitment from hospital administrators* as a facilitator was explicitly mentioned in every site. As one interviewee described, "I think [the hospital's leaders are] very committed and that's the piece of why we're still in existence." Another noted how, "We had buy-in from senior leadership in terms of the CEO knew what I was doing and wanted it to be successful." Administrative commitment itself was

characterized by descriptors such as “support,” “responsibility,” and “financial commitment.”

Commitment from clinicians was also noted as a key facilitator. As one administrator described, “…the physician organization. They’re our principal investigators. They’re the ones who allow us to function through their offices and also have been instrumental in linking us over the twenty plus years to the local hospitals as well.” Another hospital’s research nurse reflected on the importance of this commitment, even over time. “I think as the years have gone by, the physicians are more and more committed to the CCOP. I think that is recognized, or I’ve recognized that, just through the increased number of physicians doing clinical trials with our CCOP.” The involvement of nurse clinicians also reportedly facilitated CCOP participation, as seen in several of the quotes presented in Table 3.

3. Champions—Finally, related to the importance of commitment was the critical role of champions in facilitating CCOP participation. Across sites, the influence of *administrative champions* was frequently discussed. As one interviewee described of the CCOP director, “…she’s definitely been a champion. … She goes to bat for us, be it with the economy being so poor, she [works] for us to make sure we all keep our jobs and our funding and keeping operational costs down.” At another site an administrative champion was similarly lauded: “So she’s been a strong supporter and then she also helps to spread the support among the staff, whether it’s medical assistants or nurses in medical oncology here, who are very instrumental in helping to identify patients as appropriate, especially for prevention and control studies.”

Clinical champions were also important facilitators of CCOP participation. As one interviewee explained, “It is important to have a physician leader. At the start of the program, there are political and clinical issues. And if there is no physician champion who helps to drive it, you cannot get it started.” Another hospital’s research nurse described their physician champion: “He is very dedicated. …We do have tumor boards here at the hospital every week, you know, for different sites of disease. And he talks to the physicians and asks them, ‘hey, you know, why aren’t you accruing? What can we do to make it better?’” The involvement of nurses as clinical champions was also reportedly important.

DISCUSSION

The challenges interviewees’ noted that they associated with CCOP participation were common across the CCOP organizations we studied, and were consistent with reports of recent research highlighting issues such as leadership support, patient recruitment, and physician participation (e.g., Minasian et al. 2010; McKinney, Weiner, and Carpenter 2006; Beckett, Quiter, Ryan et al. 2011). Given the important role of the CCOP and growing interest in the potential of PBRNs to promote patient access to scientific advances by expanding the reach of clinical trials, our findings could be perceived as troubling to policy-makers and scientists. These challenges, however, may not be insurmountable.

While issues related to the bureaucratic requirements of the CCOP are factors that may be beyond the control of hospitals and clinicians who participate in CCOP organizations, the five challenges associated with appreciation of the CCOP’s value, limited understanding, needed workflow changes, CCOP operations, and sustaining administrative support can likely be addressed, and are explored further below in our discussion of the implications of these findings for management practice.

Our findings about the challenges these interviewees perceived to be associated with CCOP participation suggest important opportunities for the NCI to support providers’ involvement

with CCOPs by perhaps reducing some of these identified participation barriers and emphasizing the benefits of participation. For instance, developing a means for organizations to document and quantify a business case could help these CCOP providers justify and sustain their participation in the CCOP. As the results of prior studies have shown the need for quality improvement and health programs to demonstrate a business case in order to generate or sustain support from their organizations (Leatherman, Berwick, Iles, Lewin, Davidoff, Nolan et al. 2003; Reiter, Kilpatrick, Greene, Lohr, and Leatherman, 2007; Song, Robbins, Garman, and McAlearney 2011), paying attention to the challenges associated with the perceived costs and operational impacts of CCOP participation may be especially important.

In this study we have also highlighted three factors that interviewees noted could facilitate CCOP participation: commitment, champions, and awareness. These suggested facilitators of CCOP participation are notably consistent with results reported from prior research focused on efforts to diffuse and implement innovations (e.g., Sales et al. 2006; Rogers 2003; Klein and Sorra 1996), especially in health services (e.g., Helfrich, Weiner, McKinney and Minasian 2007; Beckett et al. 2011). For instance, the critical role of *champions* in efforts to implement innovations has been emphasized in studies of technology implementation and organizational change in diverse health care settings (e.g., Poon, Blumenthal, Jaggi, Honour, Bates, and Kaushal 2004; Miller and Sim 2004; Nanji, Cina, Patel, Churchill, Gandhi, and Poon, 2009). Similarly, the notion of *commitment* is important for any change to succeed over time (e.g., Poon et al. 2004; Miller and Sim 2004).

What was particularly striking is our finding about the importance of *awareness*. The notion of awareness is also consistent with diffusion of innovation theory that posits knowledge as the first of the five stages of the innovation-decision process (Rogers 2003), and prior studies that have highlighted the role of awareness in promoting behavior change (Prochaska and DiClemente 1983). More recently, Beckett and colleagues (Beckett et al. 2011) conceptualized a decision-making model incorporating the work of Prochaska and colleagues (1983) that emphasizes the importance of awareness in encouraging community physicians to participate in clinical trials research. The role of *awareness* in helping to facilitate CCOP participation was noteworthy because of its potential link to the other facilitators of *commitment* and the use of *champions* that emerged. Emphasizing and building awareness may thus help to create new champions, and, ideally, enhance commitment to CCOP participation.

Management Implications

Although the facilitators of CCOP participation were not proposed as direct solutions to the challenges raised, focusing on these three factors could conceivably help hospitals and physicians overcome CCOP participation challenges. First, emphasizing *commitment*—both administrative and clinical—can help address the challenges associated with required workflow changes, managing patient recruitment and physician involvement, and sustaining administrative support. Second, the important role of *champions* can be leveraged when solutions to CCOP-related challenges require difficult changes, difficult conversations (e.g., about patient recruitment and physician involvement), and difficult budgetary decisions. Finally, *awareness* of the CCOP and its contributions to patient care may help build the support needed to implement and maintain the CCOP over time, particularly in the presence of financial challenges and competing demands. By taking these three factors into account, the challenges associated with CCOP participation may become less burdensome as the value of this participation is better recognized and promoted.

Limitations

Our study has several limitations. First, given our sample of five purposively selected | CCOP organizations, our results represent the perceptions of the informants we interviewed, and may not be representative of informants' perceptions from different providers or CCOP organizations. However, we attempted to interview a broad sample of informants, including both administrative and clinical interviewees, and have confidence that the findings we report fairly represent interviewees' perspectives about challenges and facilitators of CCOP participation. Second, our study was constrained due to the time frame in which it occurred. While changes in CCOP participation, NCI funding, research experiences, and so forth are expected over time, we were unable to study any changes directly due to our study design involving interviews conducted at one point in time. Third, while we highlight several opportunities to overcome CCOP participation challenges, our study was not designed to determine whether focusing on these suggested facilitators would be effective in practice.

Future Research Opportunities

Future studies may be able to overcome some of the limitations of this study by considering different designs and methodological approaches. For instance, by studying CCOP organizations that have successfully navigated participation challenges over time, future research can be designed to learn more about the factors that facilitate participation, and those that lead to successful sustained performance for CCOP organizations.

CONCLUSIONS

While CCOP participation is an important component of NCI's strategy to promote PBRNs to extend access to clinical trials to new and perhaps underserved populations, the challenges of CCOP participation are not trivial. Nonetheless, improving our understanding of these barriers and potential opportunities to overcome CCOP participation challenges may help both hospitals and physicians in efforts to increase and sustain participation in the CCOP and other PBRNs, thereby helping to preserve and extend critical access to innovative medical treatment options for patients in need.

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Table 1

Key Informants Interviewed, CCOP Site and Type of Informant

Informant Type	CCOP Site A	CCOP Site B	CCOP Site C	CCOP Site D	CCOP Site E	Total
Hospital Administration	7	4	2	6	3	22
Physician	5	3	1	2	2	13
Nurse	1	2	0	3	0	6
Total	13	9	3	11	5	41

Table 2

Challenges of CCOP Participation

1	***Appreciation for the Value of a CCOP***
	• "We've had some hard-liners within the hospital's high-level administration that don't understand what a CCOP is and why we're here or what we do."
	• "I did have a meeting with the Vice-Chair of Medical Affairs two days ago and he understands cancer is a growth area. So I think that that is a good thing, but he doesn't understand how much clinical research we are doing and how important clinical research is to the future of cancer care."
2	***Understanding CCOP Operations***
	• "…there have been occasions when people have said that, 'why do they have so many staff up there? How do they justify that?' They don't realize that we're the operations office for all those other hospitals."
	• "But that [CCOP operations] also takes a lot of time to set up the right infrastructure and to organize the things that we had in control. For example, we had sites that we brought on into the department that those coordinators are still doing all their own regulatory. So then we centralized that about a year and a half ago."
3	***Affording CCOP Participation***
	• "We get no funding from [hospital] and we got no funding from [hospital] either for [our research nurse]. And we get no funding for that second nurse… We just absorbed it as part of our operational expenses."
	• "I can tell you that [health system] wanted to cut our budget by $258,000, which in my mind means 4–6 of our 31 employees. I think we've always been faced with that [budget cuts] ever since I've been here. Nobody's ever been let go, but we're always faced with that."
	• And you know, they do receive funding in indirect dollars for all of that, but some of those dollars are still utilized to help support it and make up the difference the NCI cannot provide for us in direct dollars. So if we go over in supply costs for the year the hospital often times--it's just seen as an expense where we went over and they just provide it for us."
4	***Dealing with CCOP Requirements***
	• "CCOPs have their own level of responsibilities, requirements, very grant-specific things that don't always mesh with what the strategic plan is for the hospitals. And sometimes that's difficult to work together."
	• "We have had some of the other hospitals that are in our CCOP have had some trouble following the rules and we have had to sort of be the policeman related to that. That's not easy for our staff and it takes time and effort. You've got to go out and be the policeman. And unless you are a lawman, you don't really like that work."
	• "…some of the grant nurses say, 'I would rather have someone looking my stuff over every 2 weeks because I hate the fact that I would be making a mistake for a year and then somebody finds that I did it on 5 patients.' You know, it kind of depends on your perspectives. Some of our grant nurses have said that, 'I'd rather have someone to sit with me and explain to me how they want these forms filled out and that versus waiting and in the audit and finding out I interpreted the schedule incorrectly.'"
	• "There are deviations that are going to happen! Do you think that you can treat somebody for three years--there are going to be days where they are supposed to come in February the 2nd and they came in February 3rd. So what's the big deal? The deviation is irrelevant. They call everything now a violation. How is everything a violation? And guess what? If it's Monday, and the blood test was done on Thursday before, that's four days. It's a violation because of it's not within three days. It's not even relevant to the practice. So those are the kind of things which are driving us crazy."
5	***Changing Workflow to Accommodate the CCOP***
	• "So we have transitioned. Originally we had just a lab liaison who was a lab employee that we just continually tried to work with her. … So we took over that position and now I supervise the person who is the lab liaison and so she's a research coordinator. But she walks in and out of the lab; like she works in the lab and basically directs all the research-related activities, problem solves them. So the lab people still do the processing, but she oversees making sure that the lab reqs we give them are very specific about where to send things, what to do with them. So we've found that that's worked well too."
	• "At the beginning we just had a pharmacy employee that was considered like the liaison to research and … we just kept trying to work with him on how to, you know, make things go better. Things would get lost in the pharmacy and no one would know where they put such and such and that kind of thing. … So over the years we have been able to get additional support so now we have a 0.7 [FTE], so close to full-time employee. But she is the research pharmacist for the CCOP and now she's working with the components to come up with competencies for each of the component pharmacists and things like that. …. And I think that all these things just come in time as your program gets bigger."
6	***Managing Patient Recruitment and Physician Involvement***
	• "You know I think what we're finding is that we have good intentions. We open up the trial and then it doesn't accrue and then you end up closing the trial. You know, like we have a couple breast studies that are outdated in terms of-and you know there's some breast patients that you would not treat them this way now. So there's some studies that are still open that you would say, why would you even open this up in the first place?"

- "[Physician commitment] is sporadic. You've got some really dedicated physicians who want to be involved in clinical trials and are very good at conducting clinical trials and accruals [i.e., recruiting patients to participate], and then you've got a lot who aren't. You have to be that kind of physician who sees the bigger picture and the benefit of participating. Yeah, it takes time to participate in clinical trials and talk up patients and work through the IRB submission and some of the grants. And that's often not rewarded so they have to go beyond."

7 ***Sustaining Administrative Support***

- "There is still resistance from the hospital for, you know, making sure that the CCOP pays for itself. It seems to me like the hospital wants to make money off it, rather than saying all these are just good things… I think it just values profit-making research."
- It's always a giant struggle to hire new people even though we have the money for them coming in on the grant or coming in on the research."
- "And this administration is much more focused on bottom line issues; whereas in the past, it hasn't meant as much. I mean looking at departments specifically, and determining department by department, how much is it costing."

Table 3

Key Factors Facilitating CCOP Participation

AWARENESS	
Build Understanding about Importance of CCOP	• "It's nice to have a CMO who understands the research mission and the importance of having the CCOP available." • "So I think it's again educating them to what a CCOP is and what that can bring to the practice." • " "But I do believe that there is not as much awareness as there should be. … I had the opportunity to spend about 10–15 minutes with our CEO… he knew a little about it. But as I started telling him more, he was just really interested in it." • "…they've been able to influence the new administration and educate her, the new CEO, as to the importance of who we are. He's also been taking that message up to the COO of the health system and that has helped tremendously for them to understand the value of the CCOP to their institution and what we can do for them." • "We've done a couple of different efforts. Like we've gone to radiation oncology during one of their staff meetings and done kind of an infomercial about kind of what we do, grants and things like that. We've done one for the chemotherapy nurses. There was a management meeting, at one point it was like 200 managers across the health system, and [name] and I did a presentation there. So we try to do those things as many we can and it would be great if we could do more, because I definitely do not think that there is a lot of knowledge about it." • "A lot of the oncology patients that come in are on a clinical trial. So they, you know, the nursing staff and the floor staff understand the role and they understand the importance because they are getting treatments that they might not get somewhere else. So we have gotten the message from them that they understand who we are, what we're doing and how important we are and they support us in that role. They allow our administrator to do what we need to do to keep that going." • "It's going to be nice to have people who understand what it truly can do for you, reputation-wise and downstream revenue-wise."
Keep Doctors/ Patients Informed of Trials	• "Once a month we have a physician management meeting….and [name] and I discuss any new studies coming on. And then we meet with the nurses of the main office … It kind of gets set up from the first meetings that we talk about all of the changes and do all of the research training." • "the key to the success really, is the staff engaging the physician community; not only in communicating what trials are open and who can fit into what, but being embedded in their offices. So that's what keeps the activity up." • "Every month there is a couple of page newsletter that comes out. They highlight different CCOP groups throughout the state because we've got a number of different places throughout the state besides [here] that are involved in these studies" • "The nursing staff has embedded themselves within the offices of a lot of major physician groups. So if we are in our office, we are not doing our job. We are in their offices where the patients are." • "…On the card [referenced in the article], it not only tells what trial is open, but also what's the clinical criteria to have a patient be a candidate. So it helps them to on the spot know whether that person's appropriate for the particular trial or not before they even start talking to them."
COMMITMENT	
From Hospital Administrators	• "The primary program had heavy commitment up through the CEO and also the corporate office. … the commitment is amazing." • "I would say it has extremely high support. Both, not only within our organization, but also and even at our divisional level, but all the way to our system office. We're recognized within our [multi-] hospital system as a true leader in cancer research and have the recognition for that. There's support at a very high level for the work that's done and the percentage of accruals [i.e., recruited patients participating] that we have which is pretty impressive compared to national statistics." • "I do feel that support up there is--we wouldn't be where we are without it." • "I feel like the hospital and the Vice President of Oncology feel that research is important, they're not going to let the research fail. So they'll put money into it, they'll shift funds into it." • "I think you have to recognize what the hospital is doing here too. Basically they have taken the risk of having all these pay lines and they're just accepting the risk that we're going to be able to accrue enough patients [i.e., recruit enough patients for participation] to get the accrual [i.e., patient participation] to offset the cost of some of these clinical research associates. So the biggest thing that the hospital did to help the CCOP and help themselves is to take the risk of accepting responsibility for these pay lines."

From Clinicians	• "So all the physicians and staff that migrated to that group were very supportive of it." • "Our PIs are fantastic. They support the CCOP and they support the hospitals that we go to and help." • "I mean certainly our oncologists are extremely supportive and our medical oncologists are really, they are so supportive of clinical research and so involved and so engaged in clinical research, it's just how they practice" • "I think the nurses are very committed to the CCOP. I think they, you know, support the trials and attempt to get the patients on and have good working relationships with the physicians which helps to increase the number of patients we can actually put on the studies. I think they're just very supportive of it all." • "The nurses in the oncology areas, of course, it's more work for them. But I don't hear any complaints about it. So I think they're just very committed and accepting of this is how we treat patients here."
CHAMPIONS	
Administrative Champions	• "We do have a director over our administrator that understands us as well and they're very big advocates for the CCOP because they do understand the importance of it. And they've seen because we've been here so long, they've seen the benefits that the hospital receives." • "She took over [name's] position a few years ago and we were all kind of in a slump and she brought us back and you know has changed things over time. And is trying to get all the physicians on board along with all of us, along with all of her other work to do. You know? She truly, probably, I want to say, puts in 60–80 hours a week just trying to keep everything straight." • "I think [name] lives and breathes it. I mean the whole focus of her work is the research. I think her work completely revolves around that so she brings that to wherever she is at, and does it so very well." • "Our vice president of strategic planning, which has the oncology service line under his direction--and he's the former director of the CCOP--so he comes with very in-depth knowledge of who we are, what we do, and our purpose." • "… the champion for applying to the CCOP was our clinical trial manager that oversees the oncology research coordinators, [name]. She's the one that kind of sees the most value of trying to work behind the scenes and working through that investigator relationships and things like that to try and bring everybody on board."
Clinical Champions	• "And when he came into this role as Vice President and Medical Director he had been a big champion all the way through to make sure our funding has been continued and that there have been minimal cuts if any." • "We have a new CCOP PI, [name], and thus far he has been a very good supporter as well. I think it's going to continue on for sure, for us, the patients. He's worked with other physicians for us, getting the word out there more and more that we're here. So I think that the support is going to continue and maybe even grow." • "The CCOP PI is really important. He's a consensus builder, he's a coalition builder, he is really a marketer. They're a lot of things… That PI needs to be very embracing and expansive and include people and that's really a huge role." • "He is very much a [physician] champion, gives a lot of time and energy to and probably thinks about it even more than we, than the time that we see him putting forth, I think. Whether he's out fishing or whatever, he's probably still thinking about clinical research. So he's very devoted." • "… the nurses here. They really take their job seriously, they're patient advocates and they are champions of guarding the data and making sure the data goes in clean and is correct. It's just a great group of people to work with."