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Building Successful Relationships in the PLCO Cancer Screening Trial

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Abstract

Biomedical research cannot succeed without funding, knowledgeable staff, and appropriate infrastructure. There are however equally important but intangible factors that are rarely considered in planning large multidisciplinary endeavors or evaluating their success. The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial required extensive collaborations between individuals from many fields, including clinicians, clinical trialists, and administrators; it also addressed questions across the spectrum of cancer prevention and control. In this manuscript, we examine the experiences and opinions of trial staff regarding the building of successful relationships in PLCO. We summarize, in narrative form, data collected using open-ended questionnaires that were administered to the National Cancer Institute project officers, coordinating center staff, screening center principal investigators, and screening center coordinators in 2015, about 3 years after publication of the final primary trial manuscript. Trust,

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CONFLICT OF INTEREST

The authors confirm that this article content has no conflict of interest.

respect, listening to others, and in-person interaction were frequently mentioned as crucial to building successful relationships.

Keywords

Cancer screening; collaboration; multidisciplinary; PLCO; randomized controlled trials as subject; team science

1. INTRODUCTION

Biomedical research is increasingly being conducted by large collaborative groups, which has led to more complex interactions, oversight and communication than is typical in single-investigator studies. Just as funding, knowledgeable staff, and appropriate infrastructure are critical in these large multidisciplinary efforts, so are factors colloquially known as “people skills,” which include the ability of leaders to motivate, the development of respectful and honest relationships, and manners in which to acknowledge accomplishments and foster a sense of ownership. The factors that drive successful team science, an approach to addressing research questions using collaborative efforts that “leverage the strengths and expertise of professionals trained in different fields [1],” have become of interest to biomedical researchers in recent years as large, multi-disciplinary efforts become more commonplace.

The Prostate, Lung, Colorectal and Ovarian (PLCO) (Table 1) Cancer Screening Trial was a large, decades-long randomized controlled trial that was designed to answer questions in cancer screening but was leveraged to also address research areas across the spectrum of cancer prevention and control [2]. Approximately 155,000 participants were enrolled between November 1993 and July 2001 at ten US screening centers and final results were reported between 2009 and 2012. PLCO required a multi-disciplinary approach; collaborative efforts were extensive and involved individuals with expertise in clinical trials, clinical practice, pathology, medical record abstraction, biostatistics, epidemiology, computer programming and systems management, and many other areas, including administration and financial management PLCO utilized a team science approach, with trial activities requiring frequent, often daily, collaboration between individuals and teams in different disciplines, in different environments, and with different perspectives.

PLCO was sponsored and administered by the National Cancer Institute (NCI) under federal government contracts to 10 screening centers (SCs), one coordinating center (CC), a central laboratory, a biorepository, and other entities and individuals. In this manuscript, we examine the experiences and opinions of staff at the primary trial entities (NCI, CC, SCs) regarding the building of successful relationships, a critical team science component, in PLCO. We summarize, in narrative form, data collected using open-ended questionnaires that were administered to the NCI project officers (POs), CC personnel, SC principal investigators (PIs), and SC coordinators (SCCs). We do not report on techniques that were used to resolve conflicts and other relationship difficulties because we did not collect that information. Therefore, the reader should not infer that PLCO never experienced organizational challenges even though we do not address them until the Discussion section.

2. METHODS

Open-ended questionnaires were developed for each of the three primary PLCO entities (NCI POs, CC, SCs) and administered in 2015, about 3 years after publication of the final primary manuscript. Because SCs had two primary groups, principal investigators (PIs) and SC coordinators (SCCs); a questionnaire was developed for each. The 4 questionnaires are available on request from the corresponding author. The questionnaires included a number of questions, with most falling roughly into four categories: approaches to leadership, collaboration, building of relationships, and lessons learned. The PO questionnaire asked about approaches to leadership and strategies for building trial cohesiveness. The CC, PI and SCC questionnaires all asked about the effectiveness of the POs' leadership style, opportunities afforded by the POs, and approaches to team building with staff from the other primary entities. The PI questionnaire also asked about approaches to leadership and team building with his or her PLCO staff, particularly the SCC; the SCC questionnaire also asked about the effectiveness of the PI's leadership style.

We invited NCI POs and CC and SC staff who we could contact through email. Respondents' names were only known to the first author. Two POs questionnaires were received (2 invited, one served for the entire trial and the other from the start until mid-2004), one CC questionnaire (project director who served since 1995 was invited; other CC staff also contributed to completion of the questionnaire), 5 PI questionnaires (8 invited), and 5 SCC questionnaires (7 invited). One PI questionnaire was first completed by a co-investigator and SCC at the site, and then reviewed by the PL One SCC questionnaire was completed by the two co-SCCs at that particular site.

3. RESULTS

3.1. NCI

3.1.1. Trial Responsibilities—The ultimate authority in PLCO rested with the POs. The senior PO was responsible primarily for financial matters, management issues, and interactions with NCI leadership and boards. The other PO was the trial chief statistician and responsible primarily for data integrity, coordination of data analysis, and dissemination of trial results. While their primary responsibilities were different, a strong partnership existed between the two, and neither made an important decision without the input of the other, except in the instance of issues concerning primary and secondary endpoint data (the senior PO was blinded to such information). Both POs reported that having a high-level partner with whom to discuss complex leadership issues was of great help in project management.

The POs worked directly with the CC and the SCs to ensure that trial activities were performed to rigorous scientific standards. The POs were responsible for approval of SC technical staff; they also monitored SC progress and activities. The POs were members of the PLCO steering committee, the body that provided overall scientific direction for the trial and made major decisions on operational aspects. The senior PO chaired the committee.

3.1.2. Questionnaire Responses—Both POs reported that they espoused a leadership approach that relied on inclusion, respect, positive interaction, and honest communication

with all who worked on PLCO, regardless of responsibility, education, or affiliation. They reported that SC site visits were having key role in building successful relationships, as it was on these visits that they got to know the people who were working on the trial. Each SC and the CC were visited once a year for the life of the contracts (at least 17 years for most).

At each site visit, SC staff presented to the POs on current operations, staffing, accomplishments, and challenges. Most SC staff came to those presentations, including those without a prominent role. To build a sense of inclusiveness and individual importance, the POs asked each attendee to give his or her name and role. Both POs reported that site visits provided an opportunity to demonstrate NCI's commitment and support to the trial, and to reiterate the importance of the research in which the SC was involved. One PO reported that SC staff frequently asked him about the trial or screening in general. The interactions allowed the POs to identify SC staff who could contribute to the trial in other capacities, such as manuscript preparation.

The POs reported that the twice-yearly, multiple-day, in-person steering committee meetings were critical in fostering successful working relationships. In PLCO's early years, one meeting was attended only by the POs, PIs, and leads at the CC, but the POs soon realized the potential value of having all primary trial staff meet twice a year. As a result, SCCs, medical record abstractors, data managers, and others were invited to attend both steering committee meetings. Steering committee meetings had an opening and closing session, to which all attendees were invited. During the remainder of the meeting, subsets of the larger group, based either on trial role or specific interest, met for a few hours. At meetings of those with a specific role (such as the SCCs or PIs with an interest in one of the four cancers), attendees worked together on scientific, administrative, or logistical issues, such as form revision and need for protocol changes. Subcommittees were recommended by those with additional specific interests, and if approved, the POs gave them time and resources to meet.

Informal settings at the steering committee meetings, such as coffee breaks, meals, and after-hour impromptu gatherings, allowed for relaxed interactions between the attendees and the POs. During these times, individuals could ask a question or discuss issues with the PO one-on-one. Informal settings also allowed attendees to get to know one another on a personal level. Work and personal friendships were formed.

The POs stated that, whenever possible, they strived to be colleagues rather than leaders that dictated procedure. They felt it was important to listen to the concerns of SC and CC staff and work with them to develop solutions. They reported that their practice of sharing responsibilities with and providing opportunities for SC and CC staff fostered feelings of individual ownership of the trial, which led to strong commitment and dedication to PLCO.

3.2. Coordinating Center

3.2.1. Trial Responsibilities—The CC staff worked closely with the POs, PIs, SCCs, and others. They had extensive administrative, technical, and scientific responsibilities, including scheduling and documenting of meetings, coordinating of activities related to the development of the study protocol, and developing standardized study materials, including

the Manual of Operations and Procedures. The CC developed written and verbal communication guidelines and established a protocol for development and review of new study procedures. All field materials prepared by the CC were reviewed, revised, and approved by the POs before implementation.

The CC designed, managed and implemented computer systems to support numerous SC activities, and developed documentation for those systems. They developed materials and guidelines for abstraction of information from medical records relating to diagnostic evaluation of positive screenings, cancer diagnoses, and certain other medical events; they conducted quarterly review of the data collected as part of that activity. CC staff trained SC staff and monitored progress at the SCs through production of progress reports for themselves, the SCs, and the POs. Lead members of the CC were members of the PLCO steering committee.

CC activities were managed by a project director. There were two project directors during the trial, with the second serving from 1995 on. Responsibilities of the CC project director included oversight and hands-on tasks involving all aspects of the trial. Oversight tasks included guiding the development of new procedures, and hands-on tasks included defining roles for the CC staff and establishing teams. The project director and other CC staff also met weekly with the POs.

3.2.2. Questionnaire Responses—The CC reported that the POs' strong leadership along with well-established and stated goals was a key to PLCO's success. The POs listened to the CC's concerns regarding funding, discussed requests with the CC, and strove to secure additional money so unanticipated but necessary tasks could be completed. The CC staff reported that the POs made them feel that they were part of the PLCO team, and that the POs provided opportunities not typically given to CC staff. They agreed that the POs espoused an inclusive approach.

CC staff reported that throughout the course of the trial they implemented procedures and activities to foster communication and build relationships with and among the other PLCO entities. Regularly-scheduled conference calls and in-person meetings were especially valuable when addressing challenging topics and working towards resolution of CC and SC concerns. They also provided opportunities for multi-entity and multi-site brainstorming on numerous topics, including ways to fine-tune trial operations or address new and exciting research questions. The CC established a help desk for medical record abstractors so that SCs could rapidly obtain guidance regarding complex abstractions or how best to implement the CC's abstraction instructions. During the early years of trial, the CC held in-person multi-day training sessions at their headquarters for the SCCs and medical record abstractors; these provided an opportunity for the CC staff and SCCs to get to know one another on a professional and personal level. Throughout the life of the trial, CC staff attended SC site visits, usually in conjunction with the POs, to gain first-hand knowledge and understanding of SC operations. The CC reported that such information was invaluable when problem solving was necessary from afar.

The CC established and facilitated regular calls for PIs, SCCs, the subcommittees, and special interest groups to provide opportunities for discussion, collaboration, and problem solving across all PLCO entities. Mission statements were developed to focus subcommittee activities and goals. The CC project director assigned a CC staff member to each subcommittee, and these liaisons provided administrative support, technical expertise, and other services to facilitate and foster subcommittee activities. The project director or designee worked closely with CC staff members assigned to new tasks until it was clear that the assignee was successful at that task. CC teams strove to maintain a “can do” attitude in all situations.

3.3. Screening Centers

3.3.1. Trial Responsibilities—SCs were responsible for designing procedures necessary to implement the PLCO protocol at their particular institution. They were responsible for all raw data collection; they also were responsible for local data management and data processing. The CC provided forms and basic systems to carry out most of these activities.

3.4. Principal Investigators

3.4.1. Trial Responsibilities—PIs were ultimately responsible for all SC activities. All PLCO SC staff reported directly or indirectly to the PI. PIs had a number of high-level responsibilities, including appointment of staff; first-line approval of examiner and abstracting staff; signatory on all correspondence to potential participants, enrolled participants, physicians, and medical records departments; and resolution of technical and clinical questions when appropriate. PIs also were members of the steering committee. Some PIs worked closely with their SCC, who had day-to-day responsibility for all SC operations; others chose to delegate most decision-making to their SCC.

3.4.2. Questionnaire Responses—PIs reported that they felt that PLCO was a joint effort between NCI and the other PLCO entities; they reported that the POs sought out and welcomed input from all entities, including SCs without extensive experience in clinical trials operations. One PI stated that the POs worked to understand the challenges that SCs faced, and aimed to address those challenges as effectively as they could, given their own constraints. The same PI reported that the POs welcomed and valued SC input regarding operations and trial goals, and were quick to incorporate good ideas regardless of the source. One PI reported that the POs gave SCs flexibility within protocol constraints so that the specific needs of that SC could be met. PIs also reported that the POs frequently gave credit for trial successes to the SCs, something that one PI stated had rarely happened in his experience in other large multicenter projects. Another PI noted that she did not feel that the SCs were only “being used” for their ability to enroll trial participants, a fear that clinical investigators sometimes have in studies administered by outside entities; she said that the POs worked diligently to counter that concern from the beginning of the study and as a result the PIs felt like investigators and had a very satisfying experience. The five responding PIs reported that they, along with their staff, felt that they were part of a team. PIs reported that the POs gave them and their staff many opportunities to participate in trial committees and publications; one PI mentioned that any willing volunteer was accepted as long as he or she contributed. The PIs spoke of the importance and value of meeting in person with the

POs at SC site visits and with other PIs (as well as the POs) at the steering committee meetings.

One PI reported that her center worked to be open and transparent, and that the approach was integral in developing trusting relationships with all PLCO entities. One PI stated he tried to be involved in as many aspects of the study as possible, in part so he could be a good spokesperson for the trial. One PI stated that he tried to attend and participate in all meetings by expressing his thoughts on trial operations, the needs of the SCs and the trial as a whole, and possible solutions to problems.

PIs had a range of experience when PLCO started: some had led large, multicenter research projects, while others solely had clinical experience. Regardless, all respondents spoke of the importance of having had a cohesive, functional team. PIs reported that given PLCO's complexity it was necessary to have strong, experienced staff. One PI also reported that a team approach to addressing issues, one that allowed each team member to express his or her point of view, led to consensus decisions and dedicated staff who felt respected. Some reported that team problem solving led staff to feel ownership of PLCO. PIs reported that the following were important in building strong relationships with SCCs: being honest and available; keeping staff informed of study operations, issues, changes, and high-level decisions; taking responsibility for difficult tasks; not micromanaging; and recognizing accomplishments and milestones.

3.5. Screening Center Coordinators

3.5.1. Trial Responsibilities—The SCCs oversaw all SC data collection and processing activities, trained or supervised the training of other SC staff, and oversaw SC personnel and administrative procedures. The SCCs were the SC contact point for the POs and the CC. The SCCs were responsible for successful operations at their SCs. To that end, they worked closely with SC staff, interacted with trial participants, and were knowledgeable of all SC activities.

3.5.2. Questionnaire Responses—One SCC reported that she found it helpful that the POs expressed a clear understanding of the difficult and complex task that the SCCs faced in establishing trial operations. Another SCC reported the POs made her feel like a collaborator rather than just “hired help”. SCCs reported that the POs listened to them throughout the trial and other similarly positive sentiments that reflected an approach on the part of the POs to make the SCCs feel supported, included, and appreciated. One SCC appreciated that the POs recognized her and other SC staff at site visits. Inclusion of SCCs at both annual Steering Committee meetings led, according to the SCCs, to closer relationships and deeper trust with each other and other PLCO entities, and made them feel linked to the larger PLCO community. One SCC reported that being able to put a face to a name was helpful.

One SCC said that she was available to the PI and kept him updated on the trial, which was necessary because he was housed in a different building. Other SCCs reported that they met with the PI weekly to bring each other up-to-date on trial activities. Given the PIs had other pressing responsibilities, such as clinic duties, some SCCs reported that they took on some of the simpler PI responsibilities. For example, one SCC reported checking in with clinical

departments involved in the trial to make sure those operations were progressing smoothly, while another reported taking the place of her PI on trial-wide phone calls. Some SCCs reported that they appreciated that PIs did not micromanage but were available when they needed guidance or other support. One SCC reported that even though the PI was very busy and traveled a lot, he still participated in staff retreats and team building efforts. Two SCCs reported that their PIs treated them with respect. One SCC reported that the PI maintained the philosophy that they were a team, leading to the absence of a feeling of hierarchy.

The SCCs reported that relationships with the CC staff evolved over time and grew into a strong partnership. SCCs found the practice of speaking with the CC individually each week and monthly as a group to be very useful and beneficial. In-person meetings at the steering committee meetings helped to solidify relationships that had taken root on conference calls and led to further development of effective discussion. SCCs reported that they strove to work closely with the CC to develop the best possible solutions for the trial.

The SCCs reported that the CC worked to foster solid relationships with them. The CC encouraged and supported SCC participation in steering committee activities. The SCCs were grateful that the CC organized dinners when SCCs were at CC headquarters for multi-day training, giving them a chance to interact in an informal setting and get to know one another outside of work. They enjoyed the chance to learn about one another's personal lives and things that they had in common.

The SCCs reported that they made a point to get to know one another well, and to fully welcome new SCCs when they joined the trial. They reported that they relied on each other throughout the course of the trial, providing a sounding board and assisting with problem solving. SCCs had a range of backgrounds, and were willing to share their expertise with one another. One SCC stated when the SCCs became comfortable with asking one another for advice; the group truly became a team.

4. DISCUSSION

PLCO was an extensive, decades-long research endeavor, and as is the case with any project, its success was not guaranteed from the onset. In this paper, we report on an informal querying of the four primary PLCO entities as to how strong relationships were built in PLCO, which many who worked on PLCO believe were critical in making the trial a success. Throughout the responses, we saw a number of themes: trust, respect, listening to others, and in-person interaction. In our opinion, these themes distill down to a willingness to communicate openly, honestly, and respectfully in all interactions, particularly when problems arise.

To assume that PLCO relationships were without challenges would be incorrect. Bruce Tuckman's Model of Group Development [3] includes a "storming" stage, which PLCO did experience. The storming stage is described in an NIH publication as follows [4]:

"Team members establish roles and responsibilities. This process may trigger disagreements or "turf battles" and reveal a reluctance to appreciate the perspectives and contributions of people from different disciplines or training. However, if collegial disagreement is supported

and premature pressure to consensus is resisted, people will begin to open up to one another.”

Tension did exist in PLCO, mainly at its beginning. No PLCO entity was immune or non-contributory. Questionnaire respondents reported that at times personality conflicts existed, that they were told how to do their jobs, that there was an information void, and that their opinions were not considered. Some respondents initially were concerned that NCI would not allow them to access data, publish on trial results, or give them credit for their contributions. Nevertheless, the PLCO team was able to evolve to Tuckman’s “norming” stage, one in which team members begin to work effectively with one another and build trust and respect. The team also evolved to Tuckman’s “performing” stage, the stage at which the team “works together seamlessly, focuses on a shared goal, and efficiently resolves issues or problems that emerge”. It is aspects of the norming and performing stages that we have chosen to primarily report in this manuscript, as we believe it is the most useful information for researchers who strive to have a successful research experience.

We conducted the research reported in this paper a number of years after the screening component of PLCO was completed. It clearly would have been of value to conduct it during the trial or soon after its end, but we were unfamiliar with the science of team science until recently. We recognize that our positive responses could be due to a tendency on the part of most people to remember the good rather than the bad; we also recognize that our questionnaires, which due to time constraints were not reviewed, tested or validated prior to administration, could have been written in a manner that made respondents more likely to report positive aspects of their experience. When designing the questionnaires, it did not occur to us to ask respondents to report on specific instances of tension and how they were resolved, but researchers who study the “science” of team science should consider collecting such information to provide examples of strategies that did work when a problem arose. We believe, however, that our findings are of value to other researchers; in fact, much of what we report has been reported in the team science literature as being necessary for successful team building [4, 5].

We invited the NCI POs, the CC project director, as well as a number of PIs and SCCs to participate in this project. PI responses and SCC responses were each received from 5 SCs, although only 3 SCs submitted both. Therefore, we have opinions of only half of the PLCO centers. SC staff with the most favorable experiences was probably more likely to respond, which may have resulted in more selective recall than had all been represented. We also were unable to capture the experiences of persons who worked on PLCO only briefly, perhaps those who had negative experiences and left the trial.

Multidisciplinary research efforts can be successful, but success does not guarantee that a healthy working environment was available for staff. Challenges frequently faced by team researchers include interpersonal conflicts among team members [6, 7], lack of guidance on improving team dynamics [8], discipline-based differences in collaborators’ values, terminology, methods, and work styles [8], and lack of incentive and reward systems that recognize or reward multidisciplinary research and team science [9]. The aforementioned NIH document [4] provides valuable information and advice on the challenges of team

science as well as proven strategies for improvement, and is a useful reference for researchers who want to understand and improve team dynamics and work towards more positive experiences for themselves, their colleagues, and their staff.

The recent explosion of multi-disciplinary cancer research is likely to continue. As we embrace the importance of collaboration in moving science forward, we must remember that successful collaborative relationships are as important to the success of research as rigorous application of study protocol or other scientific aspects. Resources already exist to guide the development of well-functioning teams, and we hope that the leaders of multi-disciplinary efforts consult these materials to aid in trial operations.

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Biography

Pamela M. Marcus

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Table 1

PLCO entity abbreviations.

Abbreviation	Meaning
CC	Coordinating center
PI	Principal Investigator
PO	NCI project officer
SC	Screening center
SCC	Screening center coordinator