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The Use of Community Advisory Boards in Pragmatic Clinical Trials: The Case of the Adult Day Services Plus Project

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Abstract

Community advisory boards (CABs) have become increasingly common and important in translational research in healthcare, including studies focusing on home and community-based services. CABs are composed of stakeholders who share interest in research projects and typically include patients/clients, practitioners, community members, policy makers, and researchers. CABs advise researchers on issues ranging from research design and recruitment to implementation and dissemination. In this article, the researchers detail their experiences with the CAB for a pragmatic clinical trail of Adult Day Services (ADS) Plus, an education and support intervention for family caregivers of older adults with dementia using adult day services. Lessons learned, guidelines, and best practices are then presented for developing and working with a CAB in healthcare research.

Keywords

Adult day services; translational research; community advisory board; pragmatic clinical trial

Introduction

Pragmatic clinical trials represent an increasingly popular, yet complex, evaluation design that can inform the implementation and evaluation of interventions in healthcare (Landsverk et al., 2017). These trials allow researchers to test interventions in "real world" settings as a part of usual care (Loudon, Treweek, Sullivan, Donnan, Thorpe & Zwarstein, 2013). However, conducting pragmatic trials in community-based care settings may pose particular challenges (McMillen & Adams, 2017). Recruiting and retaining research participants for the duration of the study, fostering consistent relationships with community partners in the face of administrative and staffing changes, lack of data infrastructure within the partnering

community-based organizations, and maintaining the fidelity of interventions in the field are a few of the challenges that researchers confront when conducting pragmatic trials in community or social service settings.

To move evidence into practice, "'translation' has emerged as a dominant concept" (Austin, 2018, p. 455). Translational research has several definitions, but is generally thought of as "the multidirectional integration of basic research, patient-oriented research, and populationbased research, with the long-term aim of improving the health of the public" (McGartland Rubio et al., 2010, p. 4). One of the keys to this translational process and translational research is community engagement and establishing a two-way relationship between researchers and individuals and groups who have an interest and a stake in the research (Gitlin, Winter, & Stanley, 2015). Researchers have found that the use of Community Advisory Boards (CABs) can facilitate the translational process (Minkler, Salvatore, & Chang, 2018), yet there is variability in the compositional structure and function of these advisory boards. In this article, the authors review the literature on CABs and the roles that CABs play in translational research. A case study is then presented of an advisory board used in the pragmatic trial of the Adult Day Services Plus (ADS Plus) study, an education and support intervention for family caregivers to older adults with dementia who attend adult day services (ADS). An informal analysis of qualitative data collected during ADS Plus advisory board meetings is then presented along with suggestions and 'lessons learned' to help researchers maximize the utility and functioning of CABs in translational research processes.

Community Engagement and Community Advisory Boards

Community engagement involving key stakeholders are central to models of translational research regardless of study designs, including clinical research, community-based participatory research, dissemination and implementation research, and public health research. In an effort to support community engagement in health sciences research, the U.S. Congress established the Patient-Centered Outcome-Research Institute (PCORI) in 2010. PCORI, the largest public funder of community engaged research, recognizes and supports research reflecting a continuum of engagement activities from consultation to shared leadership (PCORI, 2020). Stakeholder engagement has been recognized by the National Institutes of Health (NIH) Collaboratory as particularly important to successful pragmatic clinical trials, as pragmatic clinical trials seek to answer questions of interest to patients and care providers (Fraser et al., 2020). The definition and actualization of community engagement has evolved over the past decade, accelerated by the establishment of the National Center for Advancing Translational Sciences (NCATS) by the National Institutes of Health (NIH) in 2012. In a recent survey of institutions participating in the NIH Clinical and Translational Science Awards (CTSAs) program (Eder et al., 2018), the most commonly accepted definition of community engagement was drawn from the NIH publication,

Principles of Community Engagement:

"Community engagement is the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or

similar situations to address issues affecting the well-being of those people. It is a powerful vehicle for bringing about environmental and behavioral changes that will improve the health of the community and its members. It often involves partnerships and coalitions that help mobilize resources and influence systems, change relationships among partners, and serve as catalysts for changing policies, programs, and practices (CDC, 1997/2011, p. 9)".

This same study found that eighty percent of these institutions actualized community engagement via Community Advisory Boards (CABs), with many using more than one CAB to engage the community (Eder et al., 2018). This finding echoes an earlier survey that found eighty-nine percent of CTSAs relied upon CABs to aid in research processes and translation (Wilkens et al., 2013). CABs in health-related research are commonly defined as formalized groups of invested individuals drawn from the community (e.g., patients, community groups), healthcare (e.g., providers, practitioners), and academia and government (e.g., researchers, policymakers) that "lend their expertise, advice, and/or approval on important research decisions – some of which the researcher may not have taken into consideration without their input" (Cramer et al., 2018, p. 1034). Ideally, CABs advise the researchers regarding every aspect of the research process, from study design, to recruitment, to dissemination and serve as liaisons between the researchers and the communities of interest. In fully realized community-based participatory research studies, CABs are often empowered to identify research questions of interest, adapt or translate evidence-based interventions to more fully align with the cultural resources of the community, share funding resources with investigators, and champion the sustainability of interventions that are translated in their communities (Minkler, Salvatore, & Chang, 2018).

The widespread use of CABs as well as their composition, roles and responsibilities, and functions of CABs appear to reflect consensus regarding their importance and prominence in translational research. In a recent study of CTSAs utilizing CABs (Stewart et al., 2019), virtually every CAB included members "representing lay interests" (p. 220), such as community members, representatives of advocacy organizations, and patients.

Approximately three-quarters of CTSAs included clinicians and representatives of healthcare organizations and almost one-third included government (e.g., local, state, federal) and academic representatives. As expected, the composition of the CABs largely reflected the target population of the research and the organizations that serve that particular population, such as veterans and veteran healthcare providers, tribal representatives and tribal health providers, and older adults and aging services and healthcare providers.

The extent to which CABs engage with investigators can range along a continuum from consultation to shared leadership (Carman, Dardess, Maurer, Sofaer, Adams, Bechtel & Sweeney, 2013). The CTSAs found CABs served a number of roles and responsibilities, most commonly participating in meetings, serving as connections or liaisons between the researchers and the community, and advising researchers. Notably, the CABs were also used to aid in conducting the research (e.g., recruitment) and in translating and disseminating the findings. The CTSAs found that the feedback from CABs to be useful and "incorporated CAB feedback either somewhat (39%), a lot (52%), or completely (5%)" (p. 223).

As with every aspect of research, there can be challenges associated with the use of CABs. In NIH's *Principles of Community Engagement*, Grunbaum (2011) identified several areas that can present challenges in fully engaging the community, including, "overcoming differences between and among academics and the community, working with non-traditional communities, and overcoming competing priorities and institutional differences" (p. 110).

Establishing and maintaining trusting, reciprocal, and respectful relationships between the researchers and the community lies at the core of addressing each of these challenges. Most researchers quickly learn that effective community engagement requires time, effective and on-going communication, commonality of purpose, and relinquishing and sharing control. CABs have been found to be one of the more effective vehicles in overcoming these challenges and in ensuring that the translational process between researchers and the community is alive and thriving (Halliday et al; 2017). CABs provide "space at the table" to interested persons outside of the research team, foster relationships between academics and the community, help to provide voice and perspective for "non-traditional communities", and establish formal and informal relationships that allow for the development of empathy and understanding.

The Adult Day Services Plus Study

In this case study, we focus on the Adult Day Services Plus (ADS Plus) study and the roles that the CAB played in the conduct of this pragmatic clinical trial. Pragmatic clinical trials "are designed to determine the effect of an intervention under the usual conditions in which is will be applied" and differ from explanatory trials that "are primarily designed to determine the effect of an intervention under ideal circumstances" (Koppenaal et al., 2011, p. 1095). The ADS Plus study is a five-year, National Institute on Aging (NIA) funded project that evaluates the efficacy of an evidence-based intervention for family caregivers of older adults with dementia who attend adult day services (ADS) centers. The study also evaluates the program implementation and the experiences of ADS sites and family caregivers (Adult Day Services Plus, 2020; Gitlin et al., 2019). The ADS Plus intervention itself it is multi-component and comprehensive, consisting of education about dementia, emotional support, and strategies and skill-building on caregiver self-care and managing the challenges of dementia caregiving. The ADS Plus intervention is designed to be implemented primarily by staff working in ADS centers rather than by the researchers or external interventionists. Dementia caregivers in both the intervention and control groups (e.g., services as usual) are enrolled in the study for 12 months with anticipated outcomes of improved caregiver and care recipient well-being, prolonged use of ADS, and delayed and/or lower rates of nursing home placement for those in the ADS Plus intervention group (Gitlin et al., 2019). What makes the ADS Plus intervention unique is that fact that the focus is on the caregiver-care recipient dyad whereas most services in ADS focus almost exclusively on the care recipient. Currently in year four, approximately 200 family caregivers have been enrolled in the ADS Plus study and participant recruitment and data collection are ongoing.

To foster community engagement and aid in the conduct of the ADS Plus study, the researchers established a Translational Advisory Board (TAB) at the inception of the study and continue to engage the TAB to this day. The ADS Plus TAB emerged out of preparatory

work that began prior to receiving the grant. The researchers worked with ADS industry leaders and other researchers to ensure that implementation of the intervention was feasible on a large scale. Many of these same early collaborators would eventually be invited to serve on the TAB. The ADS Plus TAB is similar in many ways to other CABs in both composition and roles, yet there are nuanced differences that reflect the unique characteristics of this study. The original TAB composition included 14 individuals: four senior researchers in aging not on the ADS Plus study team, three ADS policymakers and administrators representing professional trade groups, and seven ADS directors. Over the course of four years, one researcher, two policymakers and administrators and three directors retired or left their positions and resigned from the TAB, leaving a total of nine current members. The researchers, policymakers, and administrators were identified and invited to join the TAB based upon their prominent roles in the field and existing relationships with the researchers. The ADS directors were identified and invited to join the TAB from a list of ADS centers that were interested in being part of the study but were not randomly selected for participation in the intervention or control group arms of the ADS Plus study. The overall goal in forming the TAB was to have a balanced group with respect to different stakeholder perspectives, including administrators, researchers, and practitioners. As previously noted, stakeholder involvement is critical to the translational process and to successful completion of pragmatic clinical trials. The TAB meets biannually for approximately one hour via electronic conferencing and the ADS Plus Principal Investigators and Co-Investigators attend and facilitate the meetings.

Experiences with the ADS Plus Translational Advisory Board

Over the past four years, the TAB has met seven times. In reviewing the minutes from these meetings and reflecting on the experiences of attending these meetings, three primary themes emerged. Note that this is not a formal qualitative analysis, rather this is an informal evaluation of the researchers' experiences of working closely with the TAB. The first theme centers on the utility and ability of the TAB to address challenges faced by the study and to aid in developing solutions that the research team could not have envisioned on their own. Engaging and activating ADS centers has been one of the more challenging problems facing the ADS Plus project team. One of the primary tasks of staff in ADS centers in this study is to actively inform family caregivers about the opportunity to participate in the study both in the intervention and the control groups. While many ADS centers have been successful in this task, other centers have not been able to actively recruit family caregivers following their initial training. The researchers were reluctant to "write off" ADS centers that were failing to recruit, especially given the investment in time and energy spend on training the staff and the randomization efforts. This issue was brought to the TAB for consideration. The researchers on the TAB encouraged the ADS Plus team to use a cost-benefit approach to keeping the dormant ADS centers in the study while investing in new ADS centers. It was determined that keeping the dormant centers and trying to reactivate them was worth the cost of continuing to include these centers, while recruiting new ADS centers. Practitioners on the TAB have also been extremely helpful in providing contextual understanding as to how shifts in census and staffing may impact recruitment efforts. Recruiting family members in the study tended to plateau or cease after a fairly vigorous start to the study. The

practitioners on the TAB reminded the research team that attendance at ADS centers tends to ebb and flow seasonally and that engaging the ADS centers during the holiday season in November and December would be challenging and not productive. This has led the researcher team to employ new engagement efforts and staging them following the holidays. Overall, the ADS Plus TAB has been instrumental in executing this study and has provided insight, practice wisdom, and the "outside eye" that helped the researchers to envision solutions to issues and challenges that tend to arise in almost every study. This was especially useful in this multi-year study and the TAB will be called upon again as we strive to move the ADS Plus intervention from this pragmatic trial to dissemination.

The second theme that emerged from the TAB meetings is that process and procedure matter. The TAB meetings were most effective when a clear was set and specific questions posed for each agenda item to alert the group to the discussion points. Augmenting the agenda with specific questions to stimulate discussions and which were tailored to the group's expertise was helpful in generating ideas, facilitating discussion, and validating each member's important role. Distributing the agenda and the questions at least one week prior to the TAB meeting was also important. Second, the composition of the TAB matters. For example, the researchers on the TAB were helpful in understanding ways that they had overcome challenges in their own projects, while the practitioners provided candid "real world" insight into the realities of the challenges faced by an ADS industry with significant financial difficulties. Relatedly, it is essential to provide safe space for all of the TAB members to contribute. Although researchers may be comfortable expressing their opinions and suggestions in a group context, that may not be the case for other stakeholder groups. Practitioners may feel intimidated by titles and degrees and retreat to the sidelines during discussions. Providing questions that are specific to practitioners and soliciting and validating their participation is critically important to capture their vantage point. The utilization of facilitation techniques such as creating specific time during meetings for practitioners to speak proved important to hearing their thoughts and ideas. Maintaining contact with TAB members at professional meetings and conferences was also found to be helpful in supporting engagement. Intentionally attending and presenting at meetings where practitioners attend, such as the National Adult Day Services Association and LeadingAge conferences, was rewarding and demonstrated commitment. Conversations in informal settings between conference sessions strengthen relationships outside of formal meetings. Consultants, administrators and providers identified their involvement on the TAB as a point of pride to their colleagues in attendance. Understanding the motivations of individuals participating in the TAB is important to assure that their own professional goals are being met through this activity.

The third theme to emerge from the researchers' reflections on the TAB meetings centers on lessons learned. First, it is vital to actually use the suggestions that the TAB provides and to inform them of the results of employing their suggestions. Essentially, do not solicit advice if you are not going to consider it and potentially apply it. During virtual meetings, ADS Plus investigators were conscious of their own contributions and reflections of the questions posed to TAB members to allow enough time for member contributions. Another lesson learned involved maintaining membership and engagement in the TAB. This was especially problematic with practitioners who tend to change jobs frequently, reflective of the tenuous

nature of the ADS industry. This was also a challenge in conducting the study over multiple years as facility ownership, administration, and staff change and are typically in flux. The ADS Plus investigators initially did not fully comprehend the rate of turnover and instability in ADS, compared to other long-term care providers. In terms of the TAB, it was important to follow those TAB members as they changed jobs or to replace them as they either lost contact or interest. No family caregivers or individuals living with dementia were invited to join the TAB as the committee was formed and began meeting after site recruitment, but before individual level recruitment began. Adding care recipients to CABs later in the research process, in particular for clustered randomized pragmatic trials, may be beneficial. Finally, history often impacts research studies, especially ones that span several years. The COVID-19 pandemic has had a dramatic impact on all sectors of the geriatric care sector. Despite the provision of what some (including these researchers) deem as essential services, many ADS centers have either closed voluntarily or have been mandated to close during this time (Serres, 2020). This has significantly disrupted the lives of ADS participants, caregivers, and providers and has resulted in a parallel disruption of the ADS Plus study. At the time of this writing, the TAB has not met since the start of the pandemic and almost all participating ADS sites have had to pause their programming. The TAB may serve its greatest role and provide support and insightful direction for next steps during this uncertain time.

Conclusion & Guidelines

In their reflections on decades long involvement with a CAB, Silvestre and colleagues (2010) concluded that partnerships with a CAB "can support the integrity of the scientific process, improve the research, benefit research volunteers, and strengthen communities by affecting policy, organizing to provide new services, and bringing resources to the community" (p. 73). The ADS Plus study is still in process, yet the benefits of establishing and maintaining the TAB has been cost effective (i.e., volunteers) and useful in providing insight and addressing study challenges. Nevertheless, it does take staffing, on-going attention, and reflection which comes at a cost to the project. As outlined in this article, there are certain considerations and actions that other researchers can take to ensure the viability and utility of CABs in their research projects. Conducting long-term pragmatic research trials in healthcare, such as the ADS Plus study, is challenging on many levels. Enlisting the assistance of the community of fellow researchers, policymakers and administrators, practitioners, and (in some cases) care recipients can provide new perspectives to researchers, energize efforts to complete long-term studies, and aid in the translation of interventions from research to practice. In the end, healthcare is about relationships. Translational research in healthcare is no different: "the research community needs to embrace a far-reaching commitment to create respectful relationships across the spectrum of constituents and an infrastructure to sustain them" (Yarborough et al., 2012, p. 313). CABs are an effective way to forge these relationships and to help translate research into practice.

The case presented in this article focused on a pragmatic clinical trial of the ADS Plus program, an intervention designed to support dementia caregivers using adult day services. While this program is specific to one target group, the following guidelines emerged that

could be applied to a wide range of pragmatic clinical trials in community-based or social service settings using CABs:

- 1. Articulate a clear role for the CAB along with upfront stated expectations and responsibilities.
- **2.** Be prepared to supplement the CAB with new members as sustaining participation and proportional membership can change over time with along study period.
- **3.** Prepare CAB meetings with well-constructed agendas which include questions and topics for discussion that members are prepared to address.
- **4.** Ensure that every member has "a place at the table" and reduce perceived power differentials that may exist among the CAB members.
- **5.** Determine a feedback loop to enable CAB members to see that their recommendations are resulting in actions.
- **6.** Acknowledge the work of the CAB members and monitor and minimize work that is superfluous.
- 7. Anticipate the impact of real-world events as studies unfold and the effects that these events may have on the CAB.
- **8.** Be cognizant of the fact that relationships lie at the core of the CAB and that building and maintaining relationships require time and energy.

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