

ETHICAL CHALLENGES IN A RANDOMIZED CONTROLLED TRIAL OF PEER EDUCATION AMONG VETERANS SERVICE ORGANIZATIONS

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ABSTRACT: EFFORTS TO INCREASE COMMUNITY members' involvement in research may create novel ethical challenges. We describe an ongoing randomized trial of a peer-delivered intervention to encourage hypertension self-management. Community members serving as peer leaders participate in subject recruitment, the informed consent process, and intervention. We describe our experience with several ethical issues that may arise when conducting research in similar settings: (1) coercion of community members, by the community, to participate either as leaders or as study subjects; (2) threats to the privacy of health information; and (3) conflict between peer leaders' roles as community members *and* study team members.

KEY WORDS: informed consent, community-based research, coercion, veterans, peer pressure, peer support, hypertension, veterans service organization, privacy, autonomy

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DESPITE CONSENSUS THAT EFFECTIVE hypertension (HTN) treatment reduces morbidity and mortality (Chobanian et al., 2003), many patients in the United States continue to have sub-optimal blood pressure (BP) control (Egan, Zhao, & Axon, 2010). For chronic diseases such as hypertension,

patient self-management skills are key contributors to good outcomes (Bodenheimer et al., 2002). Moreover, there is considerable evidence that peer-delivered interventions can have at least moderate impacts on health behaviors (Webel et al., 2010). Not surprisingly, researchers have developed and tested interventions that use community members to educate members of a variety of communities regarding cardiovascular risk reduction, including hypertension control (Alcalay et al., 1999; Balcázar et al., 2005; Brownstein et al., 2005). Extensive involvement of community members in research may increase the research program's relevance to the community and increase the likelihood and success of implementation (Ahmed & Palermo, 2010).

For the last five years, faculty and staff at the Medical College of Wisconsin and Milwaukee VA Medical Center (VAMC) have collaborated with veterans' organizations in southeastern Wisconsin (WI) to develop and test community-based interventions to promote chronic disease self-management (Hayes et al., 2010). Wisconsin is home to almost half a million veterans, most of whom are older men; 75% are over 50 years old, and 41% are over 65 (United States Department of Veterans Affairs, 2010). Our current report focuses on hypertension, though we use similar methods to address other conditions requiring extensive self-management.

We are currently completing a randomized trial comparing the effectiveness of self-management education delivered by peers to that of professional delivery of similar content. This trial involves 58 veterans groups, each of which has identified group members as representatives. These individuals participated in a range of study-related activities. We found that engaging large numbers of community members in the research process raised a number of ethical issues, including coercion to participate, threats to the privacy of health information, and uncertainty about whether the representatives were part of the study team. In order to inform other researchers using rigorous designs to evaluate community-based interventions, we describe how these issues arose in our study, and how we addressed them.

Methods

Because understanding the ethical issues requires an understanding of the community partners, the intervention, and the study design, we begin with a brief description of each. A more complete description of the intervention has been published (Hayes et al., 2010).

The Community Partner

Many older veterans belong to veterans service organizations (VSO), such as the American Legion (Legion), formed in 1919 (The American Legion, 2010), or the Veterans of Foreign Wars (VFW), formed in 1899 (Veterans of Foreign Wars of the United States, 2010). These organizations were originally formed as veteran advocacy groups but have important social roles as well. All have a strong orientation towards community service, especially for youth programs, military families, and the survivors of veterans. The local post is the primary organizational unit of a VSO. We use the term “post,” although various organizations use different terms for the equivalent organizational level (e.g., Vietnam Veterans of America (VVA) has chapters). Most posts meet monthly to conduct post business and socialize. The number of persons who attend these monthly meetings commonly ranges from 10 to 40 members. Decisions about post activities are driven by the post members themselves rather than the national organization.

We partnered with 15 VFW posts to develop a pilot intervention that was funded by a local foundation, the Healthier Wisconsin Partnership Program. Based on promising early results, we obtained funding from the Department of Veterans Affairs Health Services Research and Development (HSRD) service to conduct a randomized trial comparing a peer support intervention to an intervention consisting of a series of professional seminars covering similar topics relevant to chronic disease management of hypertension.

During the planning phases of the randomized trial, we sought input from key veterans organizations—the Legion, the VFW, the Vietnam Veterans of America (VVA), and the National Association of Black Veterans (NABVets). Once funded, we recruited representatives of these organizations and other key stakeholders to form a community advisory board (CAB). The CAB assisted the study team in communicating with VSO leadership. Feedback provided through the CAB to VSO’s leadership (e.g., state-level Legion leaders) verified that this program supported their mission—in the case of the Legion, “To provide service to veterans, their families, and their communities.” Although there were incentives

for individuals and posts, both the CAB and post representatives (reps) acknowledged the importance of recognition within the organization. For example, the CAB’s Legion representative arranged for the Department Commander to send signed letters of acknowledgment to post reps, through their post commanders.

Similarly, CAB members clarified the “command structure” and competing events within the organizations at the state and local levels. This guided decisions about timing of recruitment and enrollment activities. The CAB also helped the study team recognize key aspects of VSO culture as a whole; in particular, the idea that veterans may not be inclined to participate to help themselves, but they will come on board if it helps others. The CAB also pushed for engagement of VSO auxiliaries (membership groups for spouses), since their members were more likely to support participation in a health promotion program than the members themselves.

The Interventions

The peer support intervention was based on the pilot program—*Posts Working for Veterans’ Health (POWER)*. For this intervention, we trained one to three members of each post to serve as peer leaders. We asked these individuals to attend one 8-hour and eight 90-minute educational sessions over the 12-month intervention period. At these sessions, we gave them information relevant to hypertension self-management and their role as peer leaders. To facilitate their role as educators, we provided scripts for brief (5–10 minute) presentations that they were asked to do at subsequent post meetings. To help them gain confidence in their roles, we included role plays, debriefing after each session, and recognition for successes. We asked each peer leader to report on the POWER-related activities at their post every month.

For the professional education intervention, we worked with post representatives to identify hypertension-related topics likely to be of interest to post members and to select seminar sites and times that would be convenient to most post members. We asked the post representatives to advertise the time and location of these sessions, noting the topics and the availability of refreshments and door prizes. As recommended by the post reps for these posts, each talk had adequate time for questions and answers, and brief, bulleted handouts covering the highlights.

Study Design

The study design was a cluster randomized controlled trial. Each post that participated was randomized to

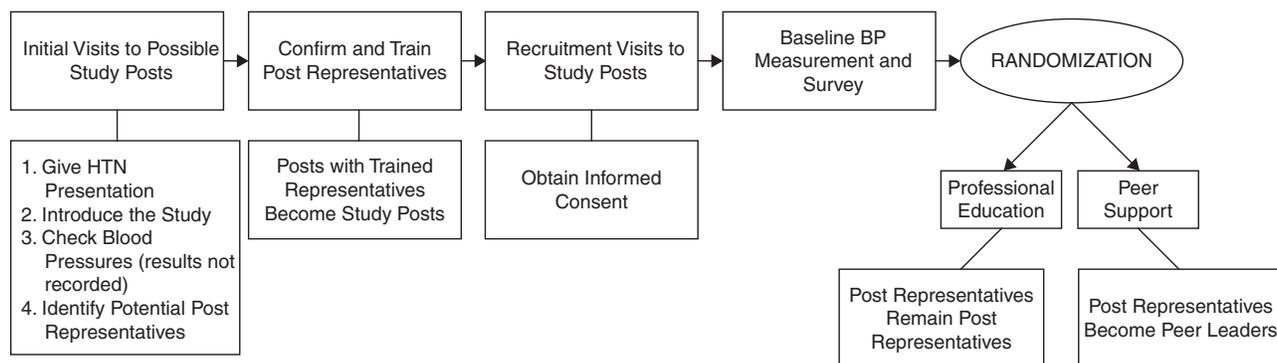


FIG. 1. Schematic of post and participant recruitment flow

either the peer support or the professional education intervention. All members of that post were targeted by the intervention. However, we only measured our outcomes among individuals with hypertension who signed an informed consent document agreeing to be a study participant. Thus, the intervention was a post program that did not involve individual consent, but the evaluation of its impact on hypertension self-management was a research study. We recruited posts for the intervention first, then recruited members within participating posts for the evaluation study.

To recruit posts, study investigators arranged in-person visits to post meetings. At these visits we described the importance of hypertension self-management and the requirements and benefits of participation. For a post to participate, post leadership had to acknowledge that participation would be at the post level and identify two individuals who were willing to serve as post representatives (post reps). We provided participating posts with blood pressure monitors, pedometers, and a weight scale, as well as \$200 annually during the two years of study activity. We also explained that for a post to be eligible for participation in the program, a significant number of post members would have to consent to participate in the evaluation study so that we could determine the impact of the interventions on outcomes. Posts typically made a decision regarding participation by majority vote; this vote occurred after the investigators had left. Post leadership communicated the decision to the study coordinator by phone.

At posts that agreed to participate, we again visited the post at a post meeting to identify members with hypertension and ask them to participate in the randomized trial evaluating the two interventions. At this recruitment visit, we gave the post two blood pressure (BP) cuffs, 12 pedometers, and a bathroom-style scale, to encourage post members to self-monitor hypertension

control, physical activity, and weight. We asked the post representatives to keep track of this equipment within their post. After enrollment was completed, we randomized that post to receive either a peer support or professional education intervention (Figure 1). We then worked with representatives of that post to deliver the assigned intervention over the next 12 months.

Results

The intervention period for this study has concluded and we are completing data collection. Thus, we present results of our recruitment efforts, but are unable to present the effect of the study intervention on blood pressure and other measures of self-management success.

Study staff made presentations about the project to 111 posts. After hearing the presentation, 59 agreed to participate. One proposed post was subsequently unable to identify any post members willing to serve as a post representative, but was linked to a post that met in the same place, so interested members could still receive the intervention. The 58 participating posts were represented by 122 post reps. We enrolled 404 participants in the evaluation study, 379 of whom provided follow-up data at 12 months. The final evaluation (at 18 months) is in progress.

Ethical Issues

COERCION OF MEMBERS TO SERVE AS POST REPRESENTATIVES OR STUDY PARTICIPANTS

Our recruitment design required that a critical mass of individuals participate in the evaluation study in order for a post to qualify for inclusion and thereby receive the benefits provided by the study. If no one was willing to be a post rep, the post could not participate in the study

and receive study benefits. In addition, if eligible post members did not consent to participate in the evaluation study, the post could not participate in the study. Thus, the post benefited only if members participated as either a post rep or an evaluation study participant. Because of the public processes whereby study staff presented the study and, later, identified participants, an individual's decision whether to participate was obvious to their peers. This raises the possibility of coercion.

Although benefiting one's community is a common motivation for research participation, it is generally unknown persons sometime in the future who benefit from research participation today (Wendler et al., 2008). In our study, where "community" may mean a group of 20 men well known to one another, such subordination of individual to group good may have been evidence of a more communal orientation (Buunk et al., 1993). Indeed, during their military service, men received medals for such behavior. Similarly, it is considered ethical for individuals to voluntarily put their health at risk to donate an organ, though with considerable oversight.

However, core ethical considerations documented in the Belmont report include respect for persons (autonomy), beneficence, and justice, but not the good of the community. In addition, we note that in the cases of combat heroism and organ donation, the benefit is seen as clear and important. In contrast, research involves providing interventions that are of uncertain value. Financial payments to study participants (and organizations) are specifically calibrated to ensure they are not coercive.

To address coercion concerns, we worked with our institutional review board (IRB) to put in place extra steps in the informed consent process. In the case of post representatives, we asked the volunteers to come to a 90-minute training session; during this session we described the study and their role in it in considerable detail, and reviewed the informed consent document. Only after obtaining informed consent did we begin the actual training process. Volunteers could choose to not attend this session or could, after hearing more detail, decline to sign the consent document; 12 individuals who initially volunteered to be post reps either declined to come to training or withdrew once they were given a detailed presentation of their role.

Throughout the process of recruiting for the evaluation study, we told potential participants that post reps would not be told which post members were participating. Similarly, we emphasized to post reps at their initial training session that study staff would gather all evaluation study data. We repeatedly stressed that the post reps

should encourage ALL post members to participate in the study intervention, and that therefore they did NOT need to know which members had agreed to be study subjects.

At the time of recruitment visits, we invited all post members in attendance to go through a blood pressure screening and eligibility evaluation. At that time, after briefly describing the study with the assistance of the post rep, we measured blood pressure (BP) for all interested individuals, and advised them regarding their goal BP. If they appeared to be eligible for the study, we provided a contact information form that they could complete and place in an opaque box. We noted that post members could simply not turn in a form, or they could make their decision private by turning in the form but not providing contact information. We left multiple copies of the informed consent document so that post members could read it at their leisure. In the days following the session, study staff contacted individuals who had turned in a form and scheduled a private visit to discuss the study in detail, answer questions, and confirm eligibility. Only at this stage were participants allowed to sign an informed consent document.

Our quantitative experience suggests that this approach had some merit. Of 519 post members who appeared to be eligible at the time of a recruitment visit, 58 declined a private enrollment visit or could not be reached, suggesting they took advantage of the opportunity to turn in a form even though they were unlikely to participate. Of the 461 who attended their private enrollment visit, 404 qualified for the study. All who qualified signed the informed consent document and became study participants. Over the course of the study, just 1% withdrew consent, even though the assessments were fairly onerous (requiring 90 minutes at baseline, 30 minutes at 6 and 18 months, and 45 minutes at the 12-month assessment) and incentive payments were small (\$60 divided among the 4 assessments). This suggests that they understood the burden of participation.

The IRB believed that this process, which provided multiple opportunities to decline to participate, was ethically permissible, even though we acknowledged that in the communal atmosphere of the post, these decisions were unlikely to remain private. A decision to withdraw was certainly known in the case of the post reps because if one withdrew, we recruited a replacement. When we asked post reps the reason they decided to volunteer for this challenging role, most indicated a desire to learn or to help others, but several said "I was 'volunteered' by my commander," or "It was my turn to do something," suggesting that community pressure drove their participation. Similarly, since our intervention encouraged

exchange of health information among peers, we believe that many individuals made it clear whether they had decided to participate in the evaluation study. Thus, although we believe that our private informed consent process provided a chance for reflection, and a chance for research staff to emphasize their free choice, it did not totally remove peer pressure.

Importantly, we note that *no* post member raised a concern that there might be community pressure to serve as a post rep or participate in the evaluation study, even though we pointed it out to all post reps during their training and to the CAB members. Indeed, CAB members actively rejected the idea that this was an ethical issue. A common observation was that the post had many opportunities to take on activities and a duty of the membership was to participate in them, sometimes as a leader, sometimes as a follower. These leaders, most of whom were quite invested in the study, acknowledged that the individual needed to be able to refuse, but maintained that individuals also needed to consider post preferences in that decision, not just their own. Previous ethical commentary has focused on the possibility that when communities or individual community members received substantial tangible benefits from participating in research, community members might not be truly free to refuse participation (Anderson, 2010; Simon & Mosavel, 2010).

The Belmont report specifically notes that the benefits (and risks) that accrue to an individual be given special weight versus societal benefits (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). However, the norms of the communities with which we work suggest that benefits that accrue to a local community may have a higher value than benefits that accrue to society at large. Clearly, this added weight is just that—something added to the already complex calculus of individual risk, individual and societal benefits, justice, and respect for autonomy—but it is a consideration that will play out in many community research projects. Ignoring such community values may make it difficult to optimally engage communities in the research process.

PUBLIC DISPLAYS OF HEALTH INFORMATION, A THREAT TO PRIVACY
Throughout the intervention period, a key message was that peer support could help an individual achieve goals. Moreover, many experts encourage self-monitoring of blood pressure and weight to guide and motivate self-management. Although paid study staff measured and recorded all study measures in private sessions, many posts openly reported and recorded weights and blood pressures that they measured using the equipment

provided at the outset of the project. Although individual posts and post leaders decided to make this private information public, the project provided an environment in which it was likely to occur. We encouraged the post reps to have BP cuffs and scales in places where they were readily available and noted that some of the most successful posts in our pilot project had elected to hold weight loss or “steps per week” contests.

Thus, we believe we indirectly caused loss of privacy of some health information, perhaps against some post members’ wishes. We have anecdotal evidence that this was noticed—post members celebrating the decision of a member with particularly high blood pressure to seek care, or hiding poor dietary choices when a peer leader was in the area. Although participants presented these as positive examples of the project’s influence, it is also possible that some members were cut off from peer support because they found it too intrusive for their comfort. At least one post that reversed an initial decision to participate cited the fact that many members felt their health status and health behaviors were no one’s concern but their own and their doctor’s.

Again, the IRB believes that our approach, developed in consultation with peer leaders who participated in the pilot project, is ethical. First, the decision to disclose is made by community members. During the initial training session for peer leaders, we canvassed the members for opinions about sharing information. We were able to provide reassurance that HIPAA regulations did not apply in this non-healthcare setting, but encouraged discussion of the ethics of information sharing. Again, utilitarian opinions were common—the peer leaders pointed out that the whole point of the project was that peers were likely to influence one another’s behavior. During our qualitative assessment of the pilot project, peer leaders and participants alike cited the increase in openness about health issues as a major benefit of the study (Hayes et al., 2010).

Second, by letting the post leadership decide how to use the post self-monitoring equipment, we empower the post to have an active role in the intervention, a key goal of CBPR. The participant/collaborators are able to “make it their own.” This means exercising the right to try out different ways of doing things, and establishing their own boundaries. While society dictates that researchers must adhere to a set of human subject guidelines that tend to be uniform across study design, members of community organizations are not (and should not) be constrained in this same way. Thus, by relinquishing control, individuals who are knowledgeable about the community—those who know each other best—set the style, pace, and tone of their interactions

(Bastida et al., 2010). Our IRB endorsed this approach, perhaps because we attempted to distinguish between the POWER “project” and the evaluation study. Thus, the project was an attempt to empower posts to use peer support and education to improve blood pressure self-management. Here, we followed our CAB’s advice to respect post autonomy. The evaluation study was an attempt to determine if the project led to measurable improvements in blood pressure and health habits. Here, we adhered closely to a study protocol, emphasizing that the data be gathered in a uniform fashion by study staff and kept private.

STUDY-RELATED DUTIES OF PEER LEADERS WHO DID NOT UNDERGO RESEARCH TRAINING

Throughout the study, our post reps served in roles that, in a traditional research study, would have been filled by paid research staff. They made informal, unscripted presentations regarding the benefits of study participation. They served as our first points of contact for questions regarding participation in the study. They actively participated in the intervention: At peer support posts, they delivered essentially all components of the intervention, and at professional education posts they determined seminar content, guided seminar logistics (e.g., timing and location), and encouraged attendance at the educational seminars.

In contrast to their extensive duties, the post reps’ and peer leaders’ training in research was limited to a single 90-minute session that also taught the basics of hypertension, use of the post equipment (e.g., BP cuffs), and the design of this study in particular. The remainder of the extensive peer leader training, and the less extensive post representative training, was directed at helping them to deliver a high-quality peer support intervention (educating them about self-management and hypertension, practicing presentation skills, reviewing educational materials, problem solving small group dynamics, etc.). In contrast to our research staff, our IRB did not require post reps to pass tests confirming their understanding of research ethics, the components of informed consent, or other basics of research involving human subjects.

We believe that this reflects in part our separation of the project from the evaluation. We designed the former to be an effort to empower the posts (i.e., the community) to take steps to improve their health. The majority of post representative efforts were in this area, although through their example and endorsement of study participation they did make vital contributions to the success of the evaluation study. We also note that the post representatives were also consulted about their role in

the study. Although many did not have hypertension and thus were not part of the main evaluation study, we also conducted a process evaluation that included describing the post reps, what they did, and what they thought of the study.

We considered the ambiguous role of the post rep/peer leader as we designed the study. In the end, we and our IRB believed that as community volunteers, they did not have the same duty to receive training as research staff. It was clear during and after the training that the time spent educating post reps on research principles was inadequate for many to achieve a good understanding of the basic tenets of research. Even though we made considerable progress in simplifying consent forms for this study, many post reps found them difficult to explain. As noted above, they accepted the need for attention to privacy issues and concerns about peer pressure to participate. However, they tended to not attend to the detailed explanation of rights in the case of injury caused by study participation and other portions they thought were irrelevant to the type of study. It is noteworthy that although the IRB required that the five-page consent be read verbatim, all the participants signed without further questions.

Finally, while it is possible that more time spent on these issues would have led to more informed post reps, formal qualitative assessments and informal interactions at various points during training suggest that they had lost interest long before our presentations on these subjects were completed. Most participants were very interested in the health topics that were the focus of the project. With so many other, more interesting things to learn from the program, participants may have viewed the research component as something to “get through” before the real lessons (biomedical topics, eating right, exercising) could be taught.

It is fortunate that our IRB agreed that our post reps did not require research training, since many of them expressed at least some frustration with the amount of paperwork involved in the consent process and/or obtaining incentive payments. A higher barrier to participation might have caused many post reps to decline participation, making our study impossible or at least much more difficult to complete.

Discussion

Working in partnership with community organizations, we were able to successfully carry out a large, complex, cluster randomized controlled trial comparing two interventions aimed at improving hypertension self-management skills. We noted that many of the post reps

became highly engaged in the project. Many peer leaders made important contributions to developing the project intervention, a goal of community-engaged research (Ahmed & Palermo, 2010). Others demonstrated substantial interest in the research aspects of the study.

During this study, we have noted several ethical issues that arose because of the complex roles of participants and the community context in which our research was conducted. Although our process evaluation data indicate that participants felt very comfortable in their roles, external observers or those unfamiliar with community-engaged research might judge that the approach we used violated principles of privacy and autonomy and paid inadequate attention to possible harms. New flexibility in guidelines may help IRBs and other research oversight bodies to ensure that human subjects protection functions well when the subjects are part of the community designing the research (Ahmed & Palermo, 2010).

More generally, if the nonscientific community comes to believe that human subjects protections make research difficult while providing no real benefit to the subjects who are being protected, societal consensus on the need for stringent research oversight may erode. Alternatively, communities may decide that the burden of working with researchers actually impedes their ability to learn whether interventions work, and take steps to avoid such entanglements. It may be that providing oversight organizations (e.g., institutional review boards) with greater flexibility in tailoring the administrative burden on participants and researchers to the risks involved would result in *more* effective human subjects protection, and greater sharing in the benefits of research.

Best Practices

Our experience suggests several best practices. First, early convening of a community advisory board provided useful guidance throughout the study. Although this may be particularly true in organizations such as VSOs, where many members have participated in leadership roles (all our VSO CAB members had held statewide offices in the past), it is likely to be an important community contact for all similar studies. Second, discussing potential human studies concerns with IRB leadership during the project design phase is likely to identify an approach that optimally protects participants, but also allows the study to be as efficient as possible. Third, identifying portions of a research project that can be carried out by individuals without specific research training may allow more community members without research experience to participate meaningfully in scientifically valid research.

Research Agenda

The field of community-based participatory research is young. A key early requirement is to simply describe the ethical issues that arise when implementing a range of study designs, working with diverse types of community organizations, and addressing a variety of health issues. This basic epidemiology is the key step at this stage. Second, we suggest that descriptive research regarding community standards for human subjects protection can inform research oversight in important ways. We must pay particular attention to standards that are viewed as excessively burdensome in the minds of the increasing numbers of community members participating in research. The societal decision to delegate research oversight to experts is not irrevocable; it is the obligation of the research oversight hierarchy to ensure that standards reflect societal consensus.

Educational Implications

Researchers should be educated regarding how community views regarding research standards may vary across communities with different cultures. This may impact the “right” ethical approach for that community, just as the culture of a patient should influence a clinician’s approach to their patient (Fadiman, 1997).

Research ethicists should work to educate the broader community regarding the societal values that are furthered by research standards that appear burdensome to individuals.

Members of institutional review boards need to familiarize themselves with the variety of community research methodologies, so that when novel studies using these methods come to their attention, they can examine the experience of participants in prior, similar studies.

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Jeff Whittle, M.D., M.P.H., is Professor of Medicine at the Medical College of Wisconsin and a Primary Care Physician at the Clement J. Zablocki VA Medical Center. He has worked with a variety of veterans organizations in conceiving and designing interventions to improve their health status. His collaborations with these groups have focused on improving self-care of hypertension, mental health, osteoarthritis, and obesity. He has visited over 100 different posts and trained over 125 peer leaders and post representatives over the last 5 years. In addition, his opinions are informed by the practice of primary care and inpatient internal medicine for 25 years, in a variety of settings, including leading the general internal medicine practice at the Kansas University Medical Center as part of his duties as the Director of the Division of Geriatrics and General Internal Medicine. Finally, he has served on the IRB or scientific review panels for a number of private and government organizations.

Kathlyn E. Fletcher, M.D., M.A., is Associate Professor of Medicine at the Medical College of Wisconsin and practices inpatient medicine at the Milwaukee VA Medical Center. She led the qualitative analysis of project impact and worked with Dr. Morzinski to develop the educational interventions for both the professional education and peer support groups. She has a long history of carrying out research on the impact of medical education activities on the outcomes and experience of patients cared for in academic medical centers.

Jeffrey Morzinski, Ph.D., has worked on projects related to the study under discussion for four years. He has worked closely with members of the study team and with community members to develop educational experiences that are most likely to help post members develop healthy lifestyle habits. He has been involved with professional

education at the Medical College of Wisconsin for 16 years, serving as the Associate Director of the Faculty Development Program throughout that period. He has also had a prominent role in undergraduate and graduate medical education at the MCW. He worked with Dr. Fletcher to design and implement the qualitative analysis of the impact of the present project.

Kristyn Ertl, B.A., C.C.R.C., is a graduate of the University of Wisconsin–Madison, and a Certified Clinical Research Coordinator for the Medical College of Wisconsin. Ms. Ertl was instrumental in obtaining funding for the pilot and randomized controlled trial described in this paper, and has served as its study coordinator since its inception. Her duties have included regular contact with peer leaders at all intervention posts, ensuring complete data on post POWER-related activities.

Leslie Patterson, M.S., is a Program Coordinator at the Medical College of Wisconsin's Department of Family and Community Medicine. She has been deeply involved with the project since joining the MCW in 2008. She is familiar with the location of nearly every medium-sized or larger town in southeastern Wisconsin, based on her extensive travel to perform post observation visits.

Wayne Jensen is a Vietnam combat veteran and a long-time member of the Milwaukee Police Force. He has served on the community advisory board for this project since its constitution in 2007. He has been active in the activities of the American Legion for many years, serving as the Commander of American Legion Post 415, Fourth District Commander, and in many other roles.

Marilyn M. Schapira, M.D., M.P.H., is an experienced investigator and primary care clinician who has carried out research on patient literacy, numeracy, and decision making for many years. She has been and is funded by the NIH and is serving as the president of the Society for Medical Decision Making. She has served as co-principal investigator for the randomized trial that is the subject of this report. She recently finished a period of service on the Medical College of Wisconsin Institutional Review Board.

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