The Role of Community Health Workers (CHWs) in Health Promotion Research: Ethical Challenges and Practical Solutions

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Abstract

This article aims to describe the role of community health workers (CHWs) in health promotion research and address the challenges and ethical concerns associated with this research approach. A series of six focus groups are conducted with project managers and investigators (n = 5 to 11 per session) who have worked with CHWs in health promotion research. These focus groups are part of a larger study funded by the National Institutes of Health titled "Training in Research Ethics and Standards" (Project TRES). Participants are asked to describe their training needs for CHWs with respect to human subject protections as well as to identify associated challenges regarding research practice (i.e., recruitment, random assignment, protocol implementation, etc.). Findings reveal a number of challenges that investigators and project managers encounter when working with CHWs on research projects involving the community. These include characteristics inherent to CHWs such as education level and personal beliefs about their own community and its needs, institutional regulations regarding research practice, and problems inherent to research studies such as training materials and protocols that cannot account for the complexity of conducting research in community settings. Investigators should carefully consider the role that CHWs have in their communities before creating research programs that depend on the CHWs' existing social networks and their propensity to be natural helpers. These strengths could lead to compromises in research requirements for random assignment, control groups, and fully informed consent.

Keywords

lay health workers; ethical research practice; research integrity; promotores

The complexity of health promotion research in community settings is ill suited to traditional research designs and methods. The use of community health workers (CHWs) in intervention research is an excellent example of the challenges that arise when traditional

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research and community intersect. Although the CHW model is becoming popular in health promotion research (Perez & Martinez, 2008; Rhodes, Foley, Zometa, & Bloom, 2007), little attention has been given to understanding and mitigating the challenges of this approach. This article will begin to address the issue by presenting examples of challenges as seen from the perspective of project managers (PMs) and principal investigators (PIs) conducting research with CHWs. Recommendations will also be presented for improving the research process, protecting research participants, and maintaining fidelity to a research design when working with CHWs. This article is meant to stimulate thinking and create a platform for further discussion around the need for changes to traditional research practices and policies when working with CHWs.

COMMUNITY HEALTH WORKERS

Community health workers have been an integral part of the health care system in Latin America and other parts of the world (Gandara, 2002; Kolker, 2008; Warrick, Wood, Meister, & de Zapien, 1992); however, their work in the United States has only recently been documented (Rhodes et al., 2007). Perez and Martinez (2007) recently detailed the history of CHWs and how they evolved to become an integral part of public health promotion in underserved and marginalized communities.

Although most of the work with CHWs in the United States has been done in Latino populations, there are several studies that attest to its effectiveness with African Americans (Parker, Schulz, Israel, & Hollis, 1998; Quinn & McNabb, 2001; Thomas, Eng, Clark, Robinson, & Blumenthal, 1998), Native Americans (Griffin, Gilliland, Perez, Helter, & Carter, 1999; Satterfield, Burd, Valdez, Hosey, & Shield, 2002), and Asian Americans (Lam et al., 2003). The literature uses many terms to describe lay health educators, including community health advisors, community health workers, lay health advisors, *doulas*, *promotores*, and *consejeras*. This article will use *community health worker* because it is used by several government agencies such as the Centers for Disease Control and Prevention (CDC, 2008) and the Health Resources and Services Administration (2008).

There are a number of advantages in having CHWs as an integral part of a research team, including increased recruitment, participation, and retention of participants; ensuring that research procedures are culturally appropriate for the target population; and providing feedback about the feasibility of using outcome assessments in the target population (Rhodes et al., 2007). In fact, CHWs may be a crucial part of the intervention effectiveness in minority and underserved populations (Brownstein et al., 2005; Navarro et al., 1998; Swider, 2002; Witmer, Seifer, Finocchio, Leslie, & O'Neil, 1995). They have also become a popular approach for accessing marginalized, difficult-to-reach populations for research purposes (Andrews, Felton, Wewers, & Heath, 2004; Lewin et al., 2005).

Studies have reported anecdotal benefits of working with a research team to the CHWs themselves including increases in self-esteem, desire to learn, community involvement, prestige in their communities, a sense of satisfaction in helping others, and a desire to continue doing so even on project completion (Booker, Robinson, Kay, Najera, & Stewart, 1997; Kim, Koniak-Griffin, Flaskerud, & Guarnero, 2004; Rodriguez, Conway, Woodruff, & Edwards, 2003; Warrick et al., 1992). These numerous benefits have made the CHW model popular for health promotion research studies (Andrews et al., 2004; Brownstein et al., 2005).

As the CHW role in research becomes increasingly more involved, so do the complications and challenges associated with carrying out their responsibilities as a research team member (Minkler, 2005; Stone & Parham, 2007). Work by Earp and colleagues illustrates some of these complications such as CHWs recruiting family and friends to meet their recruitment

goals when the research protocol stipulated that participants were to be chosen randomly (Earp et al., 2002; Earp & Flax, 1999; Flax & Earp, 1999). In addition, CHWs may introduce some degree of selection bias to a study by choosing participants who are more likely to follow all of the CHWs' intervention instructions, thus making them "look good" (Earp & Flax, 1999; Flax & Earp, 1999). Given the popularity of the CHW model in health promotion research (Rhodes et al., 2007), it is important to understand the unique challenges that are presented when CHWs adopt research roles within their communities. Many of these challenges concern the underlying conflict between the needs of underserved communities and those of research studies within these communities.

ACADEMIC–COMMUNITY RESEARCH RELATIONSHIPS

To successfully promote health in disadvantaged communities, the community itself must be empowered, respected, and given a true voice in the research process (Boutin-Foster, George, Samuel, Fraser-White, & Brown, 2008; Kelly, 2005). Unfortunately, research institution goals and community interests are often misaligned, with researchers sometimes not involving the community in the design and implementation of the research (Minkler, 2005). This leads to disempowering the community and thus perpetuating the inequality at the heart of health disparities (Boutin-Foster et al., 2008; Minkler, 2005).

Randomized intervention research designs are ill suited to community involvement, particularly if the strict methodological principles of random selection and assignment are maintained. The rigid methodology can actually undermine the effectiveness of the CHW model in changing the targeted outcomes (Conway, Woodruff, Edwards, Hovell, & Klein, 2004; Earp et al., 2002; Earp & Flax, 1999; Flax & Earp, 1999). In response to this conflict, alternative approaches such as community-based participatory research (Minkler & Wallerstein, 2003) and community–academic partnered participatory research (CAPPR; Chen, Jones, & Gelberg, 2006) have emerged. Although the role of the community is elevated to a full partner in these models, they are not without their ethical challenges. For example, confidentiality can be more difficult with CAPPR because community organizations are directly involved in collecting the data from their neighbors, friends, and families (Chen et al., 2006).

FOCUS GROUP STUDY

In response to a need for focused training to assist CHWs in carrying out their work in an ethical and responsible manner, the senior author received funding from the National Institutes of Health (NIH) to develop a culturally tailored, content-appropriate, Spanish-language research ethics curriculum, Training in Research Ethics and Standards (Project TRES). To develop the Project TRES curriculum, a series of focus groups were held with 11 principal investigators (PIs) and project managers (PMs) who worked with CHWs to conduct health promotion research in Latino communities. The primary purpose of the focus groups was to elicit feedback to guide the development of the TRES curriculum.

In addition to feedback specific to the curriculum development, the PIs and PMs shared many challenges and suggestions to working with CHWs in conducting research with communities. The purpose of this article is to highlight the ethical and practical challenges that these PIs and PMs encountered when using the CHW model, in hopes of initiating discussion and critical reflection around the challenges of having CHWs in research roles.

Participants

Participants for the focus groups were recruited by first obtaining a list of all research and community service projects involving CHWs at two universities in Southern California.

Both past and current projects were considered. Initially, 20 PIs and PMs involved with these projects were approached and asked to participate in six focus group sessions lasting 2 hr each. Of these 20, 11 agreed to participate in a majority of the sessions (at least 50%). All study procedures were approved by the SDSU Institutional Review Board for Human Subjects.

The 11 participants self-identified as PIs ($n = 3$), PMs ($n = 6$), both ($n = 1$), and neither ($n = 1$). The participant who identified as neither had been both a project manager and a principal investigator in the past for several local and federal grants. Participants were all female, 45% ($n = 5$) were Caucasian and 55% ($n = 6$) Hispanic; and most had either a master's (45%, $n = 5$) or doctoral (45%, $n = 5$) degree. Participants were 43 ± 10 years old, had worked on an average of 36 ± 104 projects that involved CHWs, and had spent an average of 11 ± 9.6 years working with CHWs.

Procedures

Focus groups were conducted in groups of 5 to 11 people with a single moderator, note taker, and research assistant who managed the audio-recording equipment. All focus groups were conducted in English. Focus group scripts were developed through consensus among the research staff of Project TRES. Probes were added to assist the moderator in guiding the conversation toward areas of interest for the project. The first focus group was designed to elicit opinions about working with CHWs as staff on research projects. The other five focus groups were designed to discuss human subject training modules that participants were given to review prior to each focus group. These modules included risks and benefits, subject involvement, informed consent, IRB background, responsibilities of those involved in research, privacy and confidentiality, and assessment.

FINDINGS

The focus group discussions revealed a variety of practical and ethical challenges associated with research using the CHW model. The challenges included characteristics inherent to CHWs such as education level and personal beliefs about their own community and its needs, institutional regulations regarding research practice, and problems inherent to research studies such as training materials and protocols that could not account for the complexity of conducting research in community settings.

There were also a variety of challenges concerning ethical research practice such as informed consent, risk communication, voluntary participation, and maintaining confidentiality. Most of the challenges reported by the PIs and PMs concerned the difficult balance that CHWs needed to maintain between the requirements of a research study (screening criteria and eligibility, randomization, and control groups) and the expectations of the communities participating in the research. The following sections present the focus group material in more detail addressing three overarching themes: research integrity, participant protection, and CHW protection.

Research Integrity

There were a number of issues that the PIs and PMs discussed with respect to research integrity when adopting a CHW model for their research. Many of these issues were not unique to the CHW model but rather reflected persistent challenges in community-based research and community–academic partnerships (Chen et al., 2006; Hagey, 1997; Minkler, 2004; Wallerstein, 1999). At the heart of many of the challenges that PIs and PMs discussed in the focus groups was the role that CHWs had in the research study versus their role in the community. Although CHWs may have been research staff, PIs and PMs stated that they were hired because they had strong connections to the community from which potential

research participants could be recruited. Whether explicit or implicit, CHWs were expected to "bridge the gap" between academic and community settings so that participants could be recruited and retained throughout the length of research studies that could last several years.

There were a number of concerns raised by the PIs and PMs regarding the maintenance of research integrity when CHWs were directly responsible for implementing a research protocol. One of the recurring issues discussed by PIs and PMs was that CHWs did not understand or embrace the idea of "randomness" and its importance to the integrity of the research project. For example, CHWs did not understand the importance of randomization strategies such as recruiting from every third house on the block and asking for the adult with the most recent birthday. In addition, because CHWs tended to believe that the research was beneficial to their community (this being a primary motivation for them to work for the study), they did not understand why all community members could not participate. This belief that the intervention is a benefit to all may lead to CHWs' ignoring the inclusion or exclusion criteria for a research study. PIs and PMs also provided examples of times when CHWs did not abide by the rules of random assignment to groups, especially when one of the groups was a control condition. There were also concerns expressed that the CHWs would share intervention information with participants in the control group in an attempt to help these participants.

Despite the training they gave the CHWs for implementing specific research protocols, PIs and PMs felt that training CHWs in basic research design was necessary to reduce potential problems with the conduct of studies. PIs and PMs thought that the CHWs had very little basic understanding of research practice and that grant resources were not adequate to provide the kind of training that most research assistants already had from bachelor's and/or master's degree programs.

Participant Protection

Informed consent—PIs and PMs expressed that one of the most challenging aspects of the research process when working with CHWs and the vulnerable populations from which CHWs were recruiting was informed consent. PIs and PMs felt certain that many CHWs did not understand the importance of the informed consent process and in many cases may not have understood much of the legal wording included in the liability sections of the document. PIs and PMs discussed their various efforts to convey the importance of the informed consent process and the requirement for participants to fully comprehend what they were signing. General consensus among the PIs and PMs was that they had not been successful in their efforts. This was especially problematic given that CHWs are the primary persons responsible for recruiting and enrolling participants in many of the PIs' and PMs' studies.

Voluntary participation—A corollary of informed consent is voluntary participation. If a person consents to participate in a study without knowing his or her rights and the benefits and risks of the research, consent may not be voluntary. In addition, there may be elements of coercion that are inherent in the bridging role that CHWs serve between communities and research studies. For example, the PIs and PMs in our focus groups mentioned that the connection between CHWs and their communities sometimes made family members, friends, and acquaintances feel obligated to participate in a study when they might not otherwise do so.

Many research studies have recruitment goals, and there is increased pressure from federal funding agencies to meet all proposed recruitment goals. Because recruitment, participation, and retention rates in research studies are very low for low-income, minority, and underserved community members (Yancey, Ortega, & Kumanyika, 2006), CHWs may not

be able to reach recruitment goals set by a granting agency despite their strong ties to the community. PIs and PMs felt that this put pressure on the CHWs to meet these recruitment goals, which in turn could lead to a variety of protocol violations, including the CHWs choosing not to convey all study risks to potential participants or the CHWs pressuring family members or friends to join studies so that they could achieve their target enrollment. Finally, PIs and PMs expressed that when CHWs recruited people from their social networks to participate, these people sometimes found it very difficult to withdraw from the study because of feelings of obligation to complete the study for the CHWs.

Confidentiality—Confidentiality was repeatedly mentioned as a challenging ethical issue during the PI and PM focus groups. For many of the PIs' and PMs' research, CHWs were usually out in the target community and in participants' homes. Maintaining confidentiality in such settings was very difficult. For example, PIs and PMs relayed stories of CHWs leaving participant contact information on their desks, placing personal data in their cars without using a locked box for transport, and using participant names when discussing the project with other members of the research team. Many of these issues were resolved with training and practice; however, more difficult to resolve were situations in the community where CHWs would interact with research participants as part of their extended network of friends and families.

CHW Protection

Participant expectations—The CHWs are primarily community members and health advocates and as such they expect to help people as part of their job. In fact, many CHWs are hired because of their natural abilities to reach out to vulnerable people in their communities (Navarro et al., 1998). PIs and PMs discussed how the CHWs felt a sense of personal responsibility for the participants and often went beyond their "research role" in an attempt to help the people in the study. The PIs and PMs also discussed how participants in their studies sometimes perceived the CHWs as health care providers. In this role, participants expected diagnoses and treatment for their own and their family's health concerns. This finding is similar to "therapeutic misconception" (Chen et al., 2006), essentially meaning that participants mistake research care for health care, which often occurs with research conducted in communities that have limited access to health services.

Research protocol—It was clear during the focus groups with the PIs and PMs that research protocols were often inadequate for dealing with the inherent complexity of research using a CHW model. For example, a PI-PM relayed a story in which a CHW working on her study put in extra personal time to help a participant access follow-up care when the participant had a positive mammography screening. At the time, there was no adverse-event protocol in place to guide the CHW in her actions. PIs and PMs relayed stories where CHWs felt obligated to assist with finding services for the research participants, regardless of whether the services were related to the research project or if the participant was in a control group.

DISCUSSION

The use of the CHW model for intervention research highlights a fundamental issue in the gap between research and practice or policy. The traditional experimental designs that have high internal validity are often not only inappropriate for community-based research but also difficult to translate into practice and ultimately policy (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; Green & Glasgow, 2006). To fully address these issues, we must not only look to culturally appropriate training methods for CHWs but also explore possibilities for adapting traditional research practices to better fit underserved community settings.

In response to the limitations of traditional research methods such as randomized controlled trials, new models for intervention research have been proposed such as pragmatic or practical clinical trials (Tunis, Stryer, & Clancy, 2003) and function-focused randomized trials (FFRTs; Hawe, Shiell, Riley, & Gold, 2004). FFRTs are better suited to community-based intervention research because they make allowances for context–intervention interactions (Hawe et al., 2004). For example, if a workshop is recognized as a mechanism for change, instead of standardizing the workshop material, the participants are able to adapt it to their specific needs. The context–intervention interaction approach of FFRTs is particularly relevant to research with CHWs because of its focus on adaptation or what is termed *function* instead of an emphasis on standardization of intervention components termed *structure*.

The focus on function allows the CHWs and the community more freedom to adapt the intervention components to different cultures, physical environments, and community needs. Lipsky (1980) applied the term *professional discretion* to describe the need to adapt rigid policies to fit real-world situations. CHWs are similar to Lipsky's street-level bureaucrats in that both joined a profession because of the desire to help the disadvantaged but feel restricted by top–down policies. By adopting a functional approach to research design, it is possible that many of the challenges relayed by the PIs and PMs in our focus groups could be avoided.

RECOMMENDATIONS

In addition to a paradigm shift to more community-centric approaches for intervention research, the focus groups revealed a number of potential solutions to some of the most difficult issues associated with having CHWs fulfill research roles.

Training

As part of the larger NIH project that funded these focus groups, a specific curriculum was developed for training CHWs in research ethics (Project TRES). A self-study guide is freely available through the project Web site (http://interwork.sdsu.edu/capri/training.html) in both English and Spanish. A "Research 101" tutorial has also been developed to complement the curriculum and is available through the project Web site as well.

The curriculum and tutorial were developed based on the feedback from the PIs and PMs and incorporate training for recruitment and selection, condition assignment, confidentiality, and informed consent. This curriculum emphasizes that whenever possible, the CHWs should be trained using specific examples from the research studies that employ them to ensure the CHWs are empowered to fulfill their role on the particular project. For example, if CHWs will be contacting participants by phone, training should include procedures specific to maintaining participant confidentiality during these contacts with using a script when leaving a message.

The majority of the literature in this area focuses on the need for extensive training in research design and protocol elements for CHWs working as research team members (Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Sciences Policy, & Institute of Medicine, 2003; Conway et al., 2004; Family Strengthening Policy Center, 2006; Hill, Bone, & Butz, 1996; Hunter et al., 2004). Hill and colleagues (1996) recommend that CHWs' training should last at least 3 months and they should receive close supervision and monitoring throughout the research study to ensure that the protocol is followed.

Roles and Responsibilities

The appropriate use of the CHW model in research with vulnerable communities may require a paradigm shift in the overall design of intervention research. At the project development level, this may require changing the roles and responsibilities of the CHWs. PIs may want to consider designing research that puts less demand on the CHW to complete tasks that may be in conflict with their role as a community health advocate. For example, instead of having the CHW randomize participants to specific conditions, it may be possible to randomize communities to conditions and have the CHW represent a specific community that participates in one arm of the research.

The CHW could be removed from the recruitment and screening role altogether and assigned to the role of interventionist or retention specialist. In this role, the CHW may feel more comfortable because he or she is providing a service to the participant while also using his or her community ties to benefit the research study. Finally, it may not be realistic for research studies to have CHWs assigned to "control" conditions with no obvious benefit to the participants. This was one of the most frequently cited challenges that PIs and PMs expressed in our focus groups. At times, CHWs would compromise the integrity of a no-treatment control group while attempting to stay "true" to the needs of their communities.

Developing Specialized Research Protocols for Underserved Communities

Throughout the focus groups it was clear that independent of the work of the CHWs, special procedures were needed for conducting research with immigrant, low-income, and underserved communities. The consent process often did not adequately reflect the culture and literacy needs of those targeted for research. For example, the informed consent process needs adequate time for participants to discuss involvement in the study with their family. This often means that there is an orientation session initially explaining the consent document, people are allowed to take the document home, and then participants bring the document back to the research team and ask any questions they or their family had about the study. In addition, the language used in both the verbal presentation and written documentation of consent should reflect the language skills and reading level of the person being recruited. These are accepted ethical practices endorsed by institutional review boards (IRBs) across the country.

IRBs should be willing to adapt the process of consent to targeted underserved populations. For example, it may be appropriate at times (e.g., undocumented individuals, persons with sensitive health condition such as HIV infection) to waive the requirement to document informed consent with a signature given that the signed document may pose greater risk to the participant than his or her actual study involvement. In those cases, the federal regulations (45 CFR 46.117) allow for the participant to determine whether he or she wants to sign the document or alternatively sign a short version of the consent form that lessens the associated risks with documentation.

LIMITATIONS

There are a number of limitations to the conclusions and recommendations from our work. The focus groups were conducted specifically to develop a curriculum for training CHWs in human subject research ethics, not to understand the challenges of using the CHW model in research, and therefore, the findings presented are in no way comprehensive. It is likely that important issues in this area have been overlooked because questions specific to this inquiry were not included in the focus groups. In addition, the sample is very small and not meant to represent the opinions of all PIs and PMs. Furthermore, the study design did not apply rigorous qualitative methods in development of the focus group questions, analysis of the data (reliability and validity checks), and interpretation of the findings (reconciling multiple

interpretations of the same transcripts). Despite the limitations, this is an important step in initiating the discussion on the redesigning of research to be better aligned with the communities in which the research is conducted.

CONCLUSIONS

Health promotion researchers have a responsibility to ensure that their research promotes social justice and empowers the members of the community in which it is conducted, including CHWs (Israel et al., 2003). By creating an ethical structure within which the CHW can work with both the research team and the target community, the challenges we have discussed may be substantially reduced and the ultimate integrity of the study design and resulting outcomes enhanced. It is also essential that researchers create an environment based on the ethical principle of respect for the community and give the community an equal voice in the process of research. This will require careful reflection and then changes in current institutional and research practices and policies.

Acknowledgments

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