Re-examining Community Based Research Protocols

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ABSTRACT *:The Wai`anae community is challenged with multiple medical, psychosocial, geographic, and economic adversities, serving primarily indigenous peoples. This is also a community with distinct cultural and political strengths and a history of community activism. Much has been written from the perspective of academia or professional organizations regarding community-based research. The purpose of this article is to re-examine research guidelines previously developed over ten years ago through the Waianae Coast Comprehensive Health Center, and to address issues which continue to significantly impact on any research conducted in the community of Wai`anae. The first issue this article will address pertains to access to conduct research through this Center. Next, the process for submitting a research proposal, and key community elements essential in research proposals will be described, followed by a discussion on "ownership" of data. An examination of the challenges discovered through research partnerships will conclude this article. (PHD 2004 Vol 11 No 1 Pages 102 - 106)*

Introduction

Guidelines and principles regarding community based research and establishing community partnerships have been described in articles primarily from academic and professional organizations[1-4]. The purpose of this article is to share community based protocols generated from the Waianae Coast Comprehensive Health Center (WCCHC) serving the community of Wai`anae. The Wai`anae community is challenged with multiple medical, psychosocial, geographic, and economic adversities. This is also a community with distinct cultural and political strengths and a history of community activism. Located on the island of Oahu, the Center has served the Wai`anae community for 32 years. The inception of the Center is credited to several years of community-driven planning efforts focused on bringing health services to the isolated rural coastline where a thriving sugar plantation had closed and left the community without medical services. Owned and operated by the community, the Center is governed by a 17-member Board of Directors, with over 50% residing in the community. In 2003, the Center provided services to 23,943 patients through 125,642 visits. The majority of patients are Native Hawaiian (51%) followed by Caucasians (18%) and Asians (17%). Socio-economic and medical coverage data shows 65% of patients being at 100% of poverty level or below and 48% receiving coverage under the State Medicaid program.

The Center is actively establishing itself as a Research Institution. A multidisciplinary Research Committee composed of staff and providers, including a representative from the Board of Directors, were formed 15 years ago, and have functioned primarily as an internal review board for proposals submitted by external researchers. All members have obtained the National Institutes of Health Research Certification.

Guidelines for considering research requests were initiated through a National Cancer Institute (NCI) funded research project, "The Wai`anae Cancer Research Project," in 1990. Two seminal documents from this project have served as a foundation for conducting research at the Center. The first, "Principles and Guidelines for Participatory Research" was developed and published in 1992[5]. "Protocols for the Publication and Dissemination of (Project) Data" was developed to articulate the principles of community "ownership" of data[5]. Ten years later, in 2002, the Center's Research Committee re-visited these documents and the role research could play in supporting the mission and goals of the Center through a strategic planning process. The strategic plan identified activities to develop further research policies and partnerships. The Research Committee implemented these policies and invited partnerships, both traditional and non-traditional, with the support of the Center's Board of Directors.

Purpose

The purpose of this article is to re-examine guidelines previously developed over ten years ago and to address issues which continue to significantly impact on any research conducted in the community of Wai`anae. The first issue this article pertains to is access to conduct research through this Center. Next, the process for submitting a research proposal, and the key community elements essential in developing a research proposals , followed by a discussion on the "ownership" of data.

An examination of the challenges discovered through research partnerships will conclude this article.

Access to Communities

Communities populated by individuals with unique demographic and clinical profiles have been the target of institutional researchers for many years. Historically, these researchers approached a community, such as Wai`anae, with a research question, beneficial intervention, or other valuable project that was implemented for some a couple of years and then discontinued as funding waned. This resulted in hard feelings among community residents - left feeling used and abandoned. Programs they came to depend upon disappeared and studies they participated in ended without an understanding of the outcome.

One of the goals of "The Wai`anae Cancer Research Project"6, was the establishment of community-based research guidelines. These guidelines focused on research that:

- Is sensitive to the culture,
- Involves community leaders and residents in planning and implementation, as well as in the development of approaches and protection of study participants,
- Creates a sense of ownership,
- Provides job training opportunities,
- Generates meaningful data,
- Establishes a cooperative working relationship between the Wai`anae community and the research agency, and
- Involves a Community Advisory Committee.

Based upon these guidelines, the Center's Research Committee, initially developed three policies by which to evaluate research proposals: a) "Research Proposals" – reviewing a proposal; b) "Student Generated Research" – reviewing a student proposal; and c) "Research Publications" – presenting results to the research committee. In addition to the previously developed guidelines, the Committee included the following questions to researchers when submitting a proposal:

- How well does the proposal fit with the mission of the Center?
- Has adequate funding been provided (what re sources are provided to WCCHC and what re sources are required from WCCHC)?
- What is the benefit to the community?
- Was the Center involved in the development and implementation of the project?
- Are the intervention strategies community-based? and
- What is the cost to the community?

Process for Submitting a Research Proposal

In the past, research proposals came to the attention of the Committee through various routes. As a result, the majority of proposals bypassed the Committee members and process altogether. Therefore, the Committee established a system and contact person to ensure consistency and reliability of the proposal review process. Interested researchers are asked to complete the "Request to Conduct Research Form," accompanied by (at a minimum) an abstract or (preferably) the full proposal. Once these documents are received, the Committee Chair contacts the researcher with questions/clarification or an invitation to meet with the Committee to discuss the proposal. The Committee meets once a month to primarily review research proposals. Expedited reviews are considered if the researcher does cannot meet the monthly proposal review date. Following review of a proposal by the Committee, a formal response letter is provided to the researcher(s). Proposals are approved, rejected, or approved pending revisions. The status of proposals is shared with the Center's providers and Board of Directors.

Key Community Elements

In an effort to establish research partnerships and clearly convey the community's research guidelines, researchers from various institutions were invited to meet with the Center's Research Committee members when?. over the past two years. These meetings provided an opportunity for the Committee and invited guest to share thoughts and beliefs on research experience, potential research questions, and areas of interest for potential partnerships. Several key elements of a research project, from a community perspective, were shared with researchers.

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Sensitivity and relevance to the community culture

Conducting research in Wai`anae requires consideration of its sensitivity and relevance to the specific ethnic group(s) targeted and to the context of the Wai`anae community. Recruitment, implementation, and analysis are significant research issues impacted by ethnicity and the culture of the community (ex:e.g. socio-economic demographics, geography, access to resources, multi-generational families, education, etc.). Intimate knowledge of the community and the operations of the Center (ex:e.g. Where and when would be the best place and time to conduct this study? Who from the Center staff should be involved?) are essential to initiating any research project through this Center.

Benefit to the community

The research process must benefit instead ofrather than "use" the community, and the interpretation and dissemination of results must be presented to for their benefit. This is not a new idea, it was raised over ten years ago by "The Waianae Cancer Research Project," yet continues to remain a challenge to researchers in articulating the benefits of their study. In an effort to ensure a beneficial outcome, the Research Committee also looks for long-term relationships with partners. Relationships are most beneficial if they are maintained over the time it takes to explore an idea or phenomenon, test an intervention, run a cost analysis, and move forward to implementation.. This approach is time and resource intensive, and requires qualitative methods to understand the target population, the organizational context of service delivery, and to the identification of factors that may influence the a research study. However, the ultimate goal of all research done with this Center and community is to change the health outcomes of the population served, and to provide practitioners with appropriate tools based on evidence[7], as they focus on making new discoveries that will help to overcome the problems and challenges of this community.

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Funding adequacy and equity

The Committee reviews the cost of the project to the Center and inquires about the support or resources the Center would receive. While the Committee recognizes that every aspect of the project cannot be funded and in-kind costs are contributed by the Center, costs that are commonly overlooked by researchers include the impact this project will have on staff time, provider productivity, and Center space. For example, a simple chart review of 100 records requires a staff person to pull all of these records, in addition to the hundreds of records pulled every day for the daily functioning of the clinics. Staff time from Information Systems is also required to generate a list of patients meeting the targeted sample criteria.

Informed consent

Informed consent requires that participants become fully informed about the research they are being asked to participate in. Appropriately approaching and educating participants on the purpose, benefits, and risks of the research project comes with a knowledge base and appreciation of the cultural context of the community. This knowledge base includes the context of language, lifestyle, appearance, and accessibility to the place (where the interview or research will be conducted).

Involvement of community

The Committee encourages researchers to consider staff and community members as co-investigators, and to engage in true collaboration. Involvement of the community during conception, development, planning, implementation, and evaluation of a project is absolutely necessary to ensure its success. This includes the review/revision of instruments and procedures at the community level. Involving community members and/or Center staff assists in identifying the best possible route for recruitment and acceptance of the research project, the best time and place for implementation, and ensures efficient access to information and resources.

Shared results

Findings from the research project must be shared with the Center and community. Prior to journal submission of an article or presentation at a conference, the Committee also expects to review the manuscript or presentations derived from research conducted through the Center. Sharing results or findings are vital to the Center particularly when they can be translated into practice.

Creating a sense of ownership

The community becomes vested in the research project when it is involved at each step of the research process. Community members are far more likely to advocate for and support future projects by the research team without going through a lengthy planning process, since an element of trust is already present.

"Ownership" of Data

Data ownership is a sensitive topic among funding agencies, community agencies, and research scientists. Protocols used by the Center today are consistent with those developed through "The Wai`anae Cancer Research Project"9. All data, about the community, are owned by the community. Data about the Center's patients are owned by the Center. In addition, data disseminated outside of the Center must be presented to the Center's Research Committee prior to sharing it with grant funders or others. This process is vital to ensuring that the Center and community are reflected in a manner that is in the best interest of the community, and is respectful and protective ofconsistent with the Health Insurance Portability and Accountability Act (HIPAA), which ensures privacy of personal health information.

Additional procedures have been developed that ensure

data requests for research projects are: a) funded, b) congruent with data elements commonly collected at the Center, c) yielding the appropriate outcome, and d) maintain the confidentiality and integrity of the data file. A multidisciplinary Data Integrity Committee (a sub-committee of the WCCHC Quality Improvement Committee) reviews data requests for research proposals. Data requests, completed through a "Data Request Form," are reviewed for: a) purpose, b) appropriateness of data elements, c) appropriately defined data elements (gender, age, time period, provider, insurance, number of visits, diagnosis, etc.), d) size of population and data file, e) approximate length of time to retrieve data requested, and f) protected health information elements. All questions and comments are directed to the person making the request to achieve the best possible data file in the most expedient way.

Challenges

The research protocols established by the Center over ten years ago have provided a valuable framework and set of principles for researchers interested in partnering or conducting research in this community. But, sSince the dissemination of these and further developed protocols, particularly with by traditional organizations, there remain challenges are still faced by this Center has faced that are inconsistent with the shared beliefs shared on community based research partnerships. Primary amongst these challenges is the issue of "partnership." A research proposal may convey a "partnership" through the content of the proposal and/or through the "support" letter attached. The challenge (and question) that has surfaced for this Committee is how funders or reviewers know that there truly is a "partnership." The research process trusts the integrity of the researchers to ensure that this is so. However, this the Center has been listed on research proposals that it was never approached about, standard support letters are sent to "just sign," and whole proposals have been changed once a support letter was sent in. For these instances, it becomes incumbent upon reviewers to not only review the scientific merit of a research proposal, but to truly know whether the integrity of the community in which the researcher intends to conduct research has been preserved. It is much more meaningful for researchers to establish a relationship with communities, work together to identify priorities/problems/concerns, and purposeful, realistic, and cost-effective strategies for addressing or resolving those concerns. Research may be one of those strategies. This is the reason long-term commitments are attractive to this Center. Working partnerships provide an opportunity for expertise to be shared in particular research, teaching, and practice areas.

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The second challenge pertains to the dissemination of findings. Although a required element on research proposals approved by the WCCHC, few research studies find their way back to the community to share their findings. Sharing research findings with participants, the community, and the Center, provides a vital route for knowledge dissemination. The acquisition of knowledge and skills empowers communities to take action – to change behavior and practice8. Research proposals approved by the Center are those which reflect the priorities of the Center, therefore, any findings would be beneficial when to examining the operations and practices of this health facility. Continuing to work with the community and Center through the dissemination phase allows researchers an opportunity to turn their findings into valid interventions for program planning, clinical intervention, or health center operation application.

Conclusion

The Committee is continuing to pursue development of a research infrastructure at the Center through consideration of: a) plans and funding for a physical facility, b) plans for long-range sustainability, c) augmentation of data collection and analysis, and d) education, training, and research career opportunities for Center staff. The Center has formally established a Research Memorandum of Understanding with the University of Hawaii at Manoa Schools of Social Work, and Nursing and Dental Hygiene. The Committee is also continuing to establishcontinues to pursue relationships with various other institutions who share a common vision.

Community based research protocols and partnerships will no doubt have a lasting and valuable impact on this Center, the health of the population served, and the skills of community members and staff. However, it is essential for researchers to invest time and energy in establishing and maintaining relationships with communities.

References

1. American Academy of Pediatrics. Ethical considerations in research with socially identifiable populations. *Pediatrics*, 2004; 113(1): 148-151.

2. DeFrancesco S, Bowie JV, Frattaroli S, Bone LR, Walker P, & Farfel MR. The community research, education, and practice consortium: Building insitutional capacity for community-based public health. *Public Health Rep*, 2002; 117: 414-418.

3. Green LW & Mercer SL. Can public health researchers and agencies reconcile the push from funding bodies and the pull from communities? *Am J Public Health,* 2001; 91(12): 1926-1929.

4. Hohmann AA & Shear MK. Community-based intervention research: Coping with the "noise" of real life in study design. *Am J Psychiatry,* 2002; 159(2): 201-207.

5. DeCambra H, Enos R, Matsunaga DS, Hammond OW. Community involvement in minority health research: participatory research in a native Hawaiian community. Cancer Control Res Rep Public Health, 1992; October.

6. Banner RO, DeCambra H, Enos R, Gotay C, Hammond OW, Hedlund N, Issell BF, Matsunaga DS, & Tsark J. A breast and cervical cancer project in a Native Hawaiian community: Wai'anae cancer research project. Prev Med, 1995; 24: 447-453.

7. Omenn GS. Caring for the community: The role of partnerships. *Acad Med,* 1999; 74(7): 782-789.

8. Flaskerud JH & Anderson N. Disseminating the results of participant-focused research. *J Transcult Nurs*, 1999; 10(4): 340-349.

9. Matsunaga DS, Enos R, Gotay CC, Banner RO, DeCambra H, Hammond OW, Hedlund N, Ilaban EK, Issell BF, & Tsark J. Participatory research in a Native Hawaiian community. *Cancer*, 1996; 78(7 Suppl): 1582-1586.

This is what knowledge really is. It is finding out some thing for oneself with pain, with joy, with exultancy, with labor, and with all the little ticking, breathing moments of our lives, until it is ours as that only is ours which is rooted in the structure of our lives
(Thomas Wolfe 1900 - 1938)