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Establishing the Infrastructure to Conduct Comparative Effectiveness Research Toward the Elimination of Disparities: A Community-Based Participatory Research Framework

Danyell S. Wilson, PhD¹, Virna Dapic, PhD¹, Dawood H. Sultan, PhD², Euna M. August, PhD², B. Lee Green, PhD^{1,2}, Richard Roetzheim, MD², and Brian Rivers, PhD¹

¹Moffitt Cancer Center & Research Institute, Tampa, FL, USA

²University of South Florida, Tampa, FL, USA

Abstract

In Tampa, Florida, researchers have partnered with community- and faith-based organizations to create the Comparative Effectiveness Research for Eliminating Disparities (CERED) infrastructure. Grounded in community-based participatory research, CERED acts on multiple levels of society to enhance informed decision making (IDM) of prostate cancer screening among Black men. CERED investigators combined both comparative effectiveness research and community-based participatory research to design a trial examining the effectiveness of community health workers and a digitally enhanced patient decision aid to support IDM in community settings as compared with “usual care” for prostate cancer screening. In addition, CERED researchers synthesized evidence through the development of systematic literature reviews analyzing the effectiveness of community health workers in changing knowledge, attitudes and behaviors of African American adults toward cancer prevention and education. An additional systematic review analyzed chemoprevention agents for prostate cancer as an emerging technique. Both of these reviews, and the comparative effectiveness trial supporting the IDM process, add to CERED’s goal of providing evidence to eliminate cancer health disparities.

Keywords

community health workers; comparative effectiveness research; health disparity; community-based participatory research; prostate cancer

INTRODUCTION

With the goal of conducting research, outreach and education, and training addressing cancer health disparities, the Center for Equal Health (CEH) was established in 2009. The CEH was composed of four interdisciplinary working groups: Administrative, Research Training and Education, Community Engagement and Outreach, and the Research cores with funding provided by the National Institute on Minority Health and Health Disparities (NIMHD) P20-Exploratory Center of Excellence mechanism. In 2010, the NIMHD and the Agency for Healthcare Research and Quality earmarked funds to support the expansion of NIMHD-funded Centers of Excellence, to establish the infrastructure to conduct comparative effectiveness research (CER) in the context of addressing and eliminating

disparities. Historically, CER methodologies have been used to assess the comparative economic impact of various treatments and services among the general population (Institute of Medicine, 2009; Manchikanti et al., 2011; Sox et al., 2010). Although an emerging application, CER methods specifically and strategically applied to eliminate disparities in health care have the potential to improve overall health outcomes in health disparate populations (Viswanathan et al., 2010). There are a limited number of systematic reviews synthesizing evidence of comparative effectiveness trials studies generating evidence of health disparities compared with the usual care mechanisms (Mullins, Onukwugha, Cooke, Hussain, & Baquet, 2010; Peek, Cargill, & Huang, 2007; Sisk et al., 2008). Therefore, to further its vision in “achieving health equity,” the CEH successfully obtained the grant and added a fifth core to its infrastructure: the Comparative Effectiveness Research for Eliminating Disparities (CERED). This article will examine the development of the CERED core’s framework for eliminating health disparities, which will be explored for its effectiveness and implementation in future publications.

BACKGROUND

The CERED core combined community-based participatory research (CBPR) principles and CER analytical methodology to conduct a pragmatic study employing the community health worker (CHW) model in the provision of information facilitating informed decision making (IDM) for prostate cancer screening among Black men in community (nonclinical) settings. This intervention was compared with prostate cancer screening decisions of Black men made from the patient–provider interactions in the usual care setting. The role of CHWs in reducing cancer health disparities is multifaceted. They improve access to health care, provide culturally appropriate health education, and provide counseling.

The CHW model is not unique to the United States. Rather, CHWs have been used widely throughout the world to improve health outcomes for various health issues such as cancer, newborn care, and infectious diseases. According to the World Health Organization (2007), the key attributes of CHWs are that they are members of the communities where they work, selected by the communities, answering to the communities for their activities, and supported by the health system but not necessarily a part of its organization. Through their actions, they bridge the cultural as well as health literacy differences between the community and the health care system, thus further decreasing the barriers to achieving health care equity.

Currently, Black men have a 60% higher incidence, have 5-year lower survival rates, and are twice as likely to die from prostate cancer in comparison with White males in the United States (American Cancer Society, 2012; Howlader et al., 2010). According to Smedley, Stith, and Nelson (2002), feelings of mistrust, fear, discrimination, and racism have all been cited as factors of concern for African Americans in particular when interfacing with the health care system. Nevertheless, they are encouraged to participate in the IDM process for prostate cancer screening when the effectiveness of the screening modalities is uncertain (Sellers & Ross, 2003). In addition, a number of studies found that many physicians believe that they make decisions under time pressure with limited information and clinical uncertainty (Hart & Bowen, 2004; Hart et al., 2008; Smedley et al., 2002), thereby

threatening the IDM process. These are barriers against implementing national recommendations on shared decision making, inhibiting the anticipated outcomes of IDM in the clinical setting, which include (a) individual risk assessment, (b) consideration of values and beliefs, (c) knowledge of risks and benefits of screening, and (d) consideration of age and life span issues (McCormack et al., 2011; Myers et al., 2011).

The CERED infrastructure intends to use a multilevel approach to overcome these barriers by involving community members in every step of the study and by adhering to the CBPR principles outlined below. CBPR has been defined as a systematic inquiry with the collaboration of those affected by the issue being studied (Harrop, Nelson, Kuratani, Mullen, & Paskett, 2012; Minkler, Blackwell, Thompson, & Tamir, 2003; Peterson & Gubrium, 2011) and its principles are as follows:

- Community Involvement to investigate their lived experiences
- Community Stakeholders participate as equals
- Colearning between community and researchers
- Community descriptions of the local social context and real-world constraints
- Community establishes congruence between the study and local reality
- Community participation
- Community group process

To uphold CBPR principles and examine if community-based education through a trained CHW with a novel digital patient decision aid (PtDA) based on iPad technology is more effective in IDM as compared with the patient–provider encounter, CERED has partnered with faith-based organizations. Churches and faith centers are considered to be culturally relevant community organizations in African American communities (Minkler et al., 2003). CERED also partnered with the Community Advisory Board, from the CEH, to develop and deliver this intervention. In the same manner, CERED researchers synthesized evidence through systematic reviews to assess the effectiveness of two emerging cancer prevention techniques using either an observational or a randomized control study design. One systematic review sought to determine the efficacy of CHWs in changing knowledge, attitudes, and behaviors in the prevention of cancer among African American adults. The second systematic review evaluated the efficacy of chemoprevention agents (natural and synthetic) in trials for prostate cancer using methodologies familiar to CER.

STRATEGIES

The purpose of this article is to describe the CERED infrastructure as outlined in Figure 1. Specifically, the article will outline how this infrastructure facilitated the (a) design of a research study grounded in CBPR, (b) the utilization of CER methods to conduct a study empowering stakeholders to take control of their health through IDM by providing them with the latest cancer prevention information, and (c) the training of a cadre of faculty, fellows, graduate students, research staff, and community members in CER.

Research Design Guided by CBPR

To establish the infrastructure for the CERED core, we based all of our activities on the CBPR principles described above. These activities included (a) evaluations of the PtDA by community- and faith-based organization members, (b) recruitment of CHWs with recommendations from the Community Advisory Board and (c) training of the CHWs and development of a module by the CHWs based on their experiences with the intervention in the community. The goal of this module is to train researchers on community perceptions of and attitudes toward community-based scientific research and researchers.

Formative evaluation of patient decision aid—CBPR principles of *community involvement, participation, and colearning between community and researchers* were employed to determine the nature of the educational materials used in the CERED study. Focus groups of Black men in community setting (a church and barbershop) were conducted to review and assess different PtDAs in terms of content, presentation, the use of graphical and pictorial depictions, and cultural relevance. On analysis of the formative evaluation of the cultural, linguistic, and literacy relevance of the topics on IDM for prostate cancer with focus group members; it was decided that the PtDA chosen for this study should include the perspective of diverse populations and be culturally tailored, comprising beliefs, family values, symbols, and traditions affiliated with African Americans.

Recruitment of CHWs—To ensure that the CBPR principle of *community stakeholders participating as equals* was followed, the Community Advisory Board of the CEH was approached for recommendation of community members to serve as CHWs in this study. The Community Advisory Board is a novel component of the CEH. This board comprises key community members who are known leaders in the Tampa Bay area who understand the impact of health disparities on the community and the importance of CHWs in improving access to care and providing culturally appropriate health education. The Community Advisory Board recommended CHWs based on their positive reputation in the community because of their involvement in politics, entertainment, and other community boards. Recommended CHWs were interviewed to assess if they were interested in the study, if their personalities meshed well with the research team, and if they were capable of conducting the research study without biasing the participants with their personal attitude toward prostate cancer screening. Four CHWs (three were recommended from the Community Advisory Board) were recruited and hired for the study.

Training of CHWs—Training of the CHWs was a vital component of CERED, and it was important that the CBPR principle of *community establishment of the congruencies between the study and local reality* was at the foundation of the training. Currently, standardized training programs of CHWs are developed in a few states, not including Florida (Perez & Martinez, 2008). Therefore, a comprehensive, didactic, and interactive CHW training curriculum was developed based on the health belief model, the core roles and competences of CHWs as defined by the 1998 Summary of the National Community Health Advisor Study (University of Arizona, 1998), and scientific research in the areas of prostate cancer. The CERED staff and scientists developed and delivered the different lectures while remaining mindful of the difference in health literacy levels and the vast social demographic

differences of the four CHWs (education level ranged from postsecondary to master's degrees, and CHWs lived in both rural and urban communities of the Tampa Bay area). The last training module was actually developed by the CHWs and titled "Teach the Researcher." This module provided feedback and recommendations for CERED researchers based on the CHWs experiences with the intervention, interactions with Black men, and literature research to support their conceptual formulations and explanations. The development of this module ensured that we addressed the last CBPR principle of *community descriptions of the local social context and real-world constraints*. The comprehensive CHW training curriculum consisted of five learning modules spanning 12 lectures outlined in Table 1.

Training occurred once a week for 1 month, covering one module per day (3–5 hours), and was evaluated through the administration of pre- and posttests. One important aspect of the training was the dissemination of training materials via distance learning using "Go to Webinars" and in the classroom setting. This method opened the training to members of the Florida's Community Health Worker Coalition and other CHWs in the Community Engagement and Outreach core of the CEH. The goal of this coalition is to ensure better labor conditions for CHWs in Florida. For this purpose, the coalition partners with the CEH and other institutions involving CHW activities.

To further enhance the preparedness of CHWs for fieldwork in the community, the CERED research team developed simulation activities. Following the completion of the training, CHWs were ready to engage and recruit Black men and promote IDM for prostate cancer prevention using the iPad technology. The "Teach the Researcher" training will occur at the end of the study. Lessons learned from all training modules will be presented in another paper highlighting this training approach.

Comparative Effectiveness Trial Design

The central component of CERED was a comparative evaluation of the effectiveness of the CHWs and an enhanced PtDA capturing IDM in community setting as compared with screening decisions in usual care settings. The design included two study arms: (a) an experimental (CHWs intervention) arm and (b) a control (usual care group) arm. A mixed-methods approach was used to evaluate the effectiveness of the enhanced PtDA and CHWs as compared with the patient–provider interaction.

Intervention—Initially all barbershops registered in the Tampa Bay area and located at zip codes having more than 10% Black residents (based on census data) were enumerated. Barbershops were placed in a random order using a random number generated by SAS (www.sas.com) software. Barbershop owners were approached in the order in which the shops were listed and shop eligibility was assessed. From this process, one Barber joined the three CHWs recruited from the list recommended by the Community Advisory Board. In addition to setting up in different barbershops that agreed to serve as a location for recruitment, CHWs used their social networks and community connections to recruit additional Black men. Black men were successfully recruited from churches, the public housing authority, places of business, and community-based organizations.

Participants had to meet specific inclusion criteria. These criteria included self-identification as African American, never having been diagnosed with prostate cancer, and being between the age of 40 and 70 years. Men who did not self-identify as African American, were younger than 40 years, were older than 70 years, or had been previously diagnosed with prostate cancer were excluded.

Participants were met by CHWs at a comfortable and familiar community setting and were asked to provide consent and complete a baseline assessment. The baseline assessment consisted of three distinct scales measuring specific domains of IDM: Prostate Cancer Knowledge, Decisional Conflict, and Decision Self-Efficacy. Following the assessment, the enhanced PtDA using iPad technology was reviewed by the participant. The next step was to fill out the posttest on the iPad. The entire intervention was lead by the trained CHWs who were able to answer any additional questions and provide an information brochure about the advantages and disadvantages of prostate cancer screening.

Follow-up occurred at 2 and 6 weeks after the intervention. Participants were contacted via telephone to complete postintervention assessments. These assessments captured the three domains associated with IDM. At the completion of the 2-week postintervention assessment, vouchers for free prostate cancer screenings were made available to participants, along with a \$20 gift card. Participants screening behavior (if the decision was made to be screened or not and why) and quality of information provided by the CHWs will be assessed at 6-months postintervention.

Control—The control arm included participants who receive prostate cancer information from physicians during a regular scheduled checkup. Eligible clinics were placed in random order using a random number generated by SAS. The clinic directors were approached in the order clinics was listed and eligibility was assessed. The study coordinator identified a contact person in each clinic to serve as a liaison between the clinic and the research team. The contact person assisted with developing the list of eligible participants and notifying study personnel of opportunities to recruit men. Participants were recruited from the clinical roster of randomly selected health care facilities in the Tampa Bay area, based on the same inclusion criteria as in the intervention. Interested participants were required to complete the informed consent documents. Subsequently, the baseline assessment was completed in the waiting area of the health care facility. On completion of their appointment with the physician, a semistructured, face-to-face interview was administered by a research assistant. Participants were also contacted at 2 weeks to complete the postintervention assessment and again at 6 months to evaluate screening behavior. It is anticipated that the principle outcome of the CERED research study will be to establish effective delivery practice strategies with current recommendations for IDM for prostate cancer screening among Black men.

Training of Research staff in CER

Members of the CERED research team were also engaged in systematic evaluation of the literature. Systematic reviews, although important to CER, are also the highest quality of evidence used during decision making in practice as part of evidence-based research.

Systematic reviews are critically appraised with limited bias as compared with traditional narrative reviews.

The core features of all reviews include a study question, data or study collection, study appraisal, and data synthesis as shown in Table 2. Systematic reviews typically have focused research questions that are health care related. Their data, including the databases used and search strategies applied, are published in the review. In addition, data extraction forms used in the systematic review ensure rigorous critical appraisal of articles that meet the selection criteria. In contrast, traditional reviews appraisal can be biased and may vary according to the authors. Last, when applicable, systematic reviews contain quantitative meta-analysis that complements the qualitative summary of the collected data (studies) to provide evidence of a favored treatment or not. A number of universities have developed evidence-based medicine hierarchy diagrams as shown in Figure 2 and at the top of these schematics are systematic reviews.

As part of the CERED team, two postdoctoral fellows were recruited and trained to conduct evidence-based research by developing systematic reviews addressing health disparities and by conducting critical appraisal of proposed research protocols developed by health care providers at the local hospitals. The informal training guided by the Center for Evidence-Based Medicine and Health Outcomes Research at University of South Florida identified multiple training mechanisms (including online, workshops, and seminars) to ensure a well rounded experience for the postdoctoral fellows. Training included the following: a 3-day Developing a Systematic Review workshop and an online nine-module training on Critically Appraising Studies. Both of these were presented by the Cochrane Eye & Vision Group at the Johns Hopkins University. In addition, the postdoctoral fellows attended a Meta-Analysis development workshop from Statistics.com, and Tuft's Clinical and Translational Science Institute's 15-module CER Survey Course. Furthermore, each postdoctoral fellow critically appraised research protocols submitted by local physicians as part of the weekly Scientific Review Committee meeting at the Center for Evidence-Based Medicine and Health Outcomes Research.

One of the systematic reviews compared the effectiveness of CHWs with various other approaches (e.g., video, printed materials, and computers) in changing the knowledge, attitudes, and behavior of African Americans as they relate to cancer prevention and education. It is important to conduct this systematic review because African Americans continue to suffer from higher cancer incidences and mortality rates (Siegel, Ward, Brawley, & Jemal, 2011). Some studies have examined the application of the CHW model with adult African Americans (Wells et al., 2011). However the overall effectiveness in delivering education to the African American population has not been evaluated in the context of cancer (Weinrich & African American Hereditary Prostate Cancer Study, 2006). This systematic review will provide that information and resolve some of the conflicting findings regarding the effectiveness of CHWs (Martinez-Donate, 2009; Viswanathan et al., 2010).

The second systematic review evaluates both natural and synthetic chemoprevention agents for prostate cancer. Globally, prostate cancer is the second most common cancer diagnosed in men, and the sixth leading cause of death from cancer (Globocan, 2008). The highest

incidence and mortality rates occur in men of African descent, globally (Globocan, 2008). Prostate cancer is an ideal candidate for chemoprevention because it has high prevalence, mortality rates, well-known molecular mechanisms, and a long latency period (Kim, 2010). Recently, apart from the discovery of newer treatments, chemoprevention agents have been at the forefront of the battle against prostate cancer. Therefore, various low-toxicity chemoprevention agents are tested via observational as well as experimental mechanisms.

A number of randomized controlled trials have shown that chemoprevention agents can reduce, induce, or have no effect on the risk of prostate cancer incidence, and we are not aware of any systematic review that evaluates all of the chemoprevention agents (Dennert et al., 2011; Ilic, O'Connor, Green, & Wilt, 2011; Lippman et al., 2009; Simon, Chen, & Bent, 2009; Stratton & Godwin, 2011; Wilt et al., 2010). To our knowledge, this will be the first comprehensive systematic review of the current chemoprevention agents (biologics, botanicals, and synthetic) addressing comparative effectiveness and safety of these agents against prostate cancer. This systematic review will evaluate the literature to develop a single source of chemoprevention studies for prostate cancer that may inform health policy decisions, patients, and physicians on current options.

DISCUSSION AND CONCLUSIONS

The CERED project's multilevel structure for community engagement, outreach, and research, as shown in Figure 1, provides a potential framework for the development of culturally appropriate activities and resources to improve IDM for prostate cancer screening among Black men. CBPR principles enable the involvement of CHWs and researchers in all study phases, including intervention design, implementation, and data collection and interpretation. CHWs in the CERED study are trained to work on multiple levels to enhance individual- and community-level knowledge and awareness, increase interpersonal communication, and support organizational involvement and engagement in order to promote prostate cancer prevention. In the same manner, training researchers to develop systematic reviews synthesizes evidence about the effectiveness of the CHW-based interventions and could have further implications in policy development. This, among other things, will recognize CHWs as valuable agents in the delivery of health care information. Furthermore, the results from the CERED project activities using CER methods to generate evidence could provide a framework for how clinicians working in prostate cancer diagnosis and treatment can support IDM among Black men. Once proven effective, the CERED infrastructural design will provide a prototype for multilevel community interventions extending beyond prostate cancer.

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FIGURE 1. Framework for Integrating CBPR and CER to create the infrastructure for the CERED project

NOTE: CBPR = community-based participatory research; CER = comparative effectiveness research; CERED = Comparative Effectiveness Research for Eliminating Disparities.

FIGURE 2. The Evidence-Based Medicine Hierarchy Displaying
Systematic Reviews as the Top Tier of Evidence Used to Affect Health Care Policies

TABLE 1**CERED Training Topics for Community Health Workers**

1	<i>Conducting Research:</i> Provide insight on the research process and how to conduct research
	<ul style="list-style-type: none"> a. Learning the Internal Review Board, Internal Review Board process b. Understanding Census Data c. Awareness of Clinical Trials
2	<i>Prostate Cancer Education:</i> Define the disease of interest and provide background information about the prostate cancer
	<ul style="list-style-type: none"> a. The Biology of Cancer b. Prostate Cancer
3	<i>Social Interactions:</i> Define the core roles and competences of CHWs, provide information on the theories of social interactions, and engage the CHWs in the health belief model to prime them to use an HBM-driven approach to facilitate IDM promotion of prostate screening with African American men
	<ul style="list-style-type: none"> a. Core Roles and Competences of CHWs b. Social Interaction Awareness c. Understanding Theory
4	<i>Building Technology Skills in Community Health Working:</i> Examine and practice operating the iPad, the survey tool, and navigating the latest apps that might be helpful in the field
	<ul style="list-style-type: none"> a. Tablet training (What can you do with your iPad) b. The Survey usage and troubleshooting c. The Survey usage and troubleshooting
5	<i>Teach the Researcher:</i> CHWs provide feedback on their experiences with the intervention in the community setting. They provide recommendation that could the study based on their interactions with African American men and combined research efforts

NOTE: CERED = Comparative Effectiveness Research for Eliminating Disparities; CHW = community health worker; HBM = health belief model; IDM = informed decision making.

TABLE 2**Comparison of Traditional Narrative Reviews and Systematic Reviews**

Core Features	Narrative Review	Systematic Review
Study question	Frequently the scope is broad	Frequently a focus clinical question
Data sources and search strategy	Databases and search strategies are not always provided, potentially biased	Databases and search strategies are required and published with the review
Article review or appraisal	Variable, and usually is author dependent	Rigorous critical appraisal, typically using a data extraction form
Synthesis	A qualitative summary	Quantitative summary (meta-analysis) if applicable, in addition to the qualitative summary

SOURCE: Cook, Mulrow, & Haynes (1997).