Can a Culturally Responsive Model for Research Design Bring Us Closer to Addressing Participation Disparities? Lessons Learned from Cancer Survivorship Studies

Introduction: Health disparities research demands the inclusion of traditionally excluded peoples. Additional complex issues weigh into health disparities or multicultural research including sociopolitical context, cultural context, network or community context, and micro-level or personal dimensions.

Conceptual Framework: This paper will present a work in progress based on psycho-oncology research: A Culturally Responsive Model for Research Design. The manuscript will describe the model’s governing principles and practices employed to address these study components: 1) purpose of the research; 2) utilization of modified or new conceptual framework and operationalization; 3) methods and procedures; 4) participant and data safety and monitoring; 5) reliable and valid instrumentation; 6) drawing valid conclusions; 7) dissemination of findings; and 8) staff training. This paper will define these issues and present the guiding principles modeled to conduct culturally responsive research and increase research integrity.

Discussion: Cancer control research is an important part of the stated commitment to reduce cancer incidence, morbidity, and mortality and to increase health-related quality of life. Ethnic minorities are overrepresented in cancer burden, yet underrepresented in research. This paper is part of a movement to articulate practical models for designing culturally responsive, multicultural research. The model may have implications for increasing ethnic minority participation in research. (Ethn Dis. 2004;15:130-137)

Key Words: Cancer, Culture, Ethnic Minority, Health Disparities, Multicultural Research, Recruitment, Research Design

INTRODUCTION

Cancer is a major health concern, second only to cardiovascular illness as the leading cause of death in the United States. Ethnic minorities experience greater morbidity, mortality, later stage at diagnosis, differential treatments, and greater incidence for many cancers.2,3 Given that ethnic minority groups are the fastest growing populations in the United States and suffer increased cancer burden, including lower five-year survival and poorer survivorship outcomes,2,3 cancer research must include diverse populations. However, a paucity of cancer control research addresses health disparities with ethnic minority and under-served patients.4,5

Health disparities and multicultural research possess their own, unique presentation to common research components. In conducting multicultural research and investigating health disparities, investigators encounter many questions with few practical answers. This paper presents A Culturally Responsive Model for Research Design that is a work in progress and a synthesis of lessons learned from the past 10 years of qualitative and quantitative investigations of health-related topics with multiethnic, socioeconomically diverse, female samples and the research literature.6-11 Practical examples are drawn from the author’s current investigations examining health disparities and health-related quality of life (HRQOL) with a multi-ethnic, socioeconomically diverse sample of breast (N=700) and cervical (N=550) cancer survivors. These cancers are among the most common forms of cancer in women across all ethnic groups.1

The model presents a conceptual framework with practical guides to address some research and ethical challenges presented in designing and conducting multicultural or health disparities research. The model may have implications for the enrollment and recruitment of diverse ethnic groups into research studies.

Conceptual Framework

The model organizes health disparities and multicultural research design into two domains, the pre-investigational and the investigational. The pre-investigational factor consists of four contextual domains that are discussed by several authors and include the sociopolitical context, cultural context, network or community context, and micro-level or personal dimensions.4,5,12-20 The investigational factor includes eight study design domains: 1) purpose of the research; 2) conceptual framework and operationalization; 3) methods and procedures; 4) participant and data safety and monitoring; 5) staff training; 6) reliable and valid instrumentation; 7) drawing valid conclusions; and 8) dissemination.

Pre-Investigational Factors

Sociopolitical Context

The sociopolitical context recognizes the fact that, in the United States, ethnicity is an unfortunate proxy for poverty. A significant number of African Americans (23%), Asian/Pacific Islanders (10%), Latinos (21%), and Native Americans (32%) live at or near poverty level.6 Furthermore, the sociopolitical context is marred by historical, discriminatory experiences of minority popu-
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Cultural Context
Culture is defined as a system of shared beliefs and practices passed from one generation to another; culture impacts health-related beliefs, including attitudes and beliefs about cancer.\textsuperscript{6} Other cultural factors include spirituality/faith, language, acceptable means of communication, and attitudes towards personal disclosure.\textsuperscript{6,7,16} In the United States, non-English speaking and under-served individuals are systematically excluded because of difficulty and costs associated with translation, administration and validation of measures. Moreover, stereotypes of minorities as difficult to contact and unwilling to disclose may further contribute to reluctance of researchers to actively recruit minorities.

Network or Community Context
The network or community context refers to social aspects, including the familial response to the research enterprise and to a particular study.\textsuperscript{19} Brown et al discusses this phenomenon as accept-

Investigational Factors
Purpose of the Research
The purpose of any study is an integral part of the social responsibility component of being a researcher. Researchers should ask the difficult question: “Why am I doing this study?” If the answer falls along the line of: “Health disparity research is the new priority area for NIH or NCI”; then proceed with some caution. If the answer falls along the line of: “Health disparity is a major public health concern, and I may contribute to reducing the burden of cancer,” this mission leads to a greater community-minded purpose and survivor-compassionate approach that probably extends beyond the hypotheses. The purpose of the research should include at least one deliverable community benefit that can be highlighted when the study is presented to the community. The cervical survivorship study includes a community forum to discuss the impact of cervical cancer on women’s lives and diverse communities in Southern California.

A genuine concern for the community of interest enables: 1) a trusting relationship with community leaders and service providers who can help a study succeed within the community\textsuperscript{15,19,21-23}; 2) culturally and contextually grounded research question(s); and 3) a more comprehensive, compassionate institutional review board (IRB) application.

Without endorsement of community leaders, researchers will have difficulty gaining the trust of community members that is essential for participation. Often community leaders will present the researcher and his/her study to the

Additional factors, particularly those of low socioeconomic status (SES), are more likely to have comorbid conditions that exclude them from research participation, particularly if study inclusion criteria are too narrow.\textsuperscript{6,15} For example, African Americans are very likely to be hypertensive; Latinos and Native Americans are more likely to be diabetic.
community, this increases the credibility of the investigators and the project. Researcher-community partnerships are vital for the successful participation of ethnic minority and underserved populations. Therefore, multicultural studies should include a community advisory board empowered to guide appropriate components (e.g., staff selection and training, recruitment and enrollment procedures, and instrumentation) of the study from beginning to end. The advisory board should be initiated during the grant writing process and convened before the study is fully developed and implemented.

The second component of the purpose of the study is the research question(s) or what new information the findings will contribute to the literature and clinical practice. If the research question focuses on ethnic differences primarily, these findings contribute to the literature only, with little applicability to clinical practice. However, if the research question investigates new, under-explored dimensions, these findings hold the promise of advancing the science as well as clinical practice. Thus, survivors and their loved ones directly benefit. For example, the specific aims of these survivorship studies are to: 1) examine the HRQOL and psychosocial impact of cancer on the lives of African-American, Asian-American, Latina, and Caucasian women; 2) assess HRQOL from a culturally and socio-ecologically consistent framework; 3) assess applicability of standard measures of HRQOL in a multiethnic sample; 4) develop a predictive model of HRQOL to identify risk factors and the role of sociocultural mediators (e.g., spirituality, familial context, acculturation level, etc) in cancer survivorship in a sample that includes large numbers of ethnic minority women.

Finally, concern for the community promotes the completion of a more cohesive, participant-centered institutional review board (IRB) application, including recruitment materials and consent forms, that results in greater attention to participant and data safety and monitoring and may reduce the IRB’s concerns about risk. Therefore, a genuine interest for the target population forms the foundation on which the study builds, and engenders cultural and socioecological relevance. This genuineness may enhance a more positive overall study experience for the investigator(s), as well.

The Use of Modified or New Theoretical or Conceptual Frameworks in Multicultural and Health Disparities Research

A critical element of good research is the theoretical foundation. A well-organized theory provides a framework to: 1) grasp and make sense of the topic or area of interest; 2) govern the definition and conceptualization of the domains of interest; 3) generate hypotheses; 4) guide the measurement and instrumentation; and 5) ground the interpretation of the findings. A brief discussion of the modification of the quality of life theoretical framework to add the cultural and socio-ecological domains is presented below. This is one example of enhancing the contextual responsiveness and therefore the utility and validity of theoretical foundations for application to multicultural and health disparity studies.

The Expanded Health Related Quality of Life (HRQOL) Framework: A Contextual Model. Health-related quality of life (HRQOL) is a multidimensional construct that assesses physical, functional, emotional, and social well-being relevant to some major, often chronic, illness. The survivorship conceptual framework under development, A Contextual Model of HRQOL, adds cultural and socio-ecological dimensions to the traditional HRQOL framework. These dimensions are often not assessed in HRQOL studies. The Contextual Model guided the methods, hypotheses, and instrumentation used in the survivorship studies and was adapted for an intervention study with HIV positive women. Overall, preliminary results suggest that the model is robust and accounts for at least 50% of the variance in predicting HRQOL. Culturally and socio-ecologically responsive domains were derived from qualitative and quantitative studies, and the cancer, multicultural, and psychological literature and added to the traditional HRQOL framework. The domains of the Contextual Model for HRQOL are demographic context, life burden, cultural context, healthcare system context, and personal context.

Demographic Context. Ethnicity is conceptualized as the integration of geographic area of ancestral origin and culture. Socioecologic status includes SES, life burden, and social support. Ethnic and socioecologic status can impact cancer histology, incidence, mortality, stage at diagnosis, survival, care of the patient, and the survivorship experience. Ethnic status is an unfortunate proxy for SES as ethnic minorities are over-represented among lower-SES groups. Researchers must therefore delineate ethnic group membership from SES and socioecologic context.

Life Burden. Life burden is highly related to SES, and its influence on healthcare delivery has been documented. However, its effect on cancer survivorship is not well understood. While certain socioecologic factors may increase a woman’s risk for psychosocial and quality of life distress, other socioecologic factors may mitigate the negative impact of breast cancer. Many studies have documented the positive effects of social support on psychosocial adjustment and coping with cancer, but few include ethnic minority survivors.

Cultural Context. Culture influences health beliefs, practices, and overall well-being. The relationship between culture and survivorship outcomes has not been adequately studied. The culture paradigm in this framework includes identity, acculturation, interconnectedness, attitudes, beliefs, and spirituality.
Healthcare System Context. Ethnic minorities and under-served persons are overrepresented in low SES groups and thus have diminished access to health care due to high costs, lack of adequate health insurance, and long distances between premier treatment hospitals and economically challenged communities. Research demonstrates that ethnic minorities receive differential and inferior care; they often lack continuous, comprehensive, and state-of-the-art medical care. Further, ethnic minorities may experience difficulty in the patient-physician relationship because of culture-based and language differences in communication and treatment practices.

Methods and Procedures

In designing culturally responsive research, considering multiple methodologies and methods of data collection is important; these contribute to increasing the sample size and validity. Multiple methodologies may include combining qualitative and quantitative methods. Qualitative methods can provide necessary information about areas and populations where little is known, such as the influence of cultural and socioecologic contexts on health disparities in cancer survivorship. Data is collected via narratives, and the information promotes a deeper understanding and the generation of new hypotheses. Multiple data collection strategies may include key informants, focus groups, and in-depth, individual interviews for qualitative methods and medical chart reviews, mailed surveys, telephone interviews, face-to-face discussions, or proxy interviews for quantitative methods.

Subjects and Sampling. In recruiting diverse populations, simple random sampling from one site can be detrimental to obtaining the desired sample. In the author’s studies, cancer survivors were recruited from community agencies, hospitals, and the California Cancer Surveillance Program (CSP) in order to obtain ethnic and socioeconomic diversity. Additionally, multiple sampling methods, including population-based, stratified and snowball techniques, were used to increase the access to the available population of survivors and to over-sample African-American, Asian-American, and Latino participants, who are traditionally underrepresented.

Recruitment Procedures. The first step in recruitment is building trust and credibility with the agencies and providers who serve and advocate for underserved peoples. Community agencies are the gateway to underserved populations; therefore, developing a mutually beneficial relationship is the stepping stone to successful inclusion. These relationships often take a great deal of the investigator’s time and personal energy. However, this investment is essential to demonstrate genuine concern for communities of color. Sincerity is demonstrated by: 1) personal, social, and political orientation and involvement with the community of interest; 2) inclusion of co-investigators from the community of interest; and 3) generativity or giving back to the community in financial, technical, and/or professional support. Community agencies function with stretched budgets and staff who put in long hours at reduced compensation; they are often ruled by a passion and dedication to serve the under-served. Therefore, researchers who are not committed to the agency’s mission may be viewed as a hazard to their already vulnerable clients.

Enrollment Procedures. Very few studies have outlined and evaluated enrollment strategies. In the author’s studies, procedures to enhance the survivors’ trust levels and interest in sharing their cancer experience were implemented. Potential participants were mailed a recruitment packet containing: 1) an invitation letter that detailed the study by using culturally relevant information; 2) informed consent forms; and 3) a postage-paid, return envelope for returning signed consent forms. The documents were available in English, Spanish, Chinese, Japanese, and Korean. A toll-free number was provided for interested individuals to contact the principal investigator. This initial notification by mail demonstrates respect and ethical compliance. However, ethnic minority populations generally do not respond in large enough numbers to mailed surveys. Therefore, well-trained, culturally-linguistically competent and sensitive research staff placed follow-up telephone calls to those who had not responded within two weeks of the mailing to: 1) verify the correct contact information; 2) introduce the researchers and purpose of the study; 3) discuss the informed consent (eg, participation entails 60–90 minute interview) and payment as a token of appreciation for participation; 4) address concerns; and 5) screen for eligibility. During the telephone conversation the actual enrollment takes place for most ethnic minorities. Rapport with a linguistic and culturally competent research assistant who practices the seven principles presented in the participant safety and monitoring section below builds trust and enhances the likelihood that survivors will be interested in sharing their cancer experience and participating in the study.
Participant and Data Safety and Monitoring

Seven principles set the groundwork for participant and data safety and monitoring in all research involving human subjects, however these principles are particularly poignant in a multicultural context. The seven principles are: respect, beneficence, and justice, truth, informed consent, confidentiality, and non-maleficence.

Language Competence. Staff and researchers are required to meet the linguistic and literacy need of the participants. It is both ethically responsive and humanistic to create a research team and all subject contact materials that can communicate effectively with the study participants. Language competence is essential for true informed consent and the validity of the study instruments.

Cultural Competence. Staff possesses knowledge and sensitivity to participants’ cultural origins, historic and current sociopolitical group status, and personal socioecologic and cultural context. In creating a research team the investigator will be wise to assess for ethnic and cultural competency. Language and cultural competencies are probably the most important facilitators of research credibility and may prevent problematic ethical situations.

Ethical Conduct. A high degree of professionalism and respect is fundamental to conduct human subjects research. Knowledge of legal matters governing human subjects’ participation is essential. Currently, all investigators are obligated to abide by Health Insurance Portability & Accountability Act effective April 2003. Additionally, the Belmont Report, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, articulates the basic ethical principles that guide the conduct of research with human subjects. These principles were defined in the report as basic to the protection of human subjects: respect, beneficence, and justice.

True informed consent must be obtained from each participant. True informed consent means that the participant clearly understands all study requirements (eg, time and effort) and voluntarily, without coercion, agrees to participate conditionally.

In addition, data should be viewed as a representation of participant’s or patient’s life stories. Therefore, all data should be kept safely locked and accessible to the appropriate study team members only.

Mission. The research team should share the belief that the study is purposeful: the knowledge and understanding gained from the research can offer some benefit to participants or the target population, particularly those who are underserved.

Empathy. Ability to genuinely experience and express compassion for the individual participant as well as the individual participant is critical in gaining participants’ trust. Additionally, empathy is essential for the facilitation of disclosure and thus the accuracy of the responses.

Graciousness. Sincere gratitude is expressed to each participant who shares her cancer experience with the study. Additionally, in these studies, small tokens of appreciation are offered (a pen that serves as a convenient writing tool to complete the assessments is mailed with the survey and a $10 gift certificate). Further, a follow-up response is provided to every participant’s request or issue communicated via writing or over the telephone.

Credibility. The research team, including interviewers, is required to have basic knowledge about the illness, as well as resources available and accessible to participants. Further, the credibility of the research team is enhanced when all the previous 6 principles are addressed.

These seven principles form the foundation of risk management and human subject’s protection; these principles together with the staff training create a respectful, culturally responsive research environment.

Instrumentation

Research has documented the importance of culturally appropriate and valid instruments with multicultural samples. The challenges and solutions presented in the development of reliable, valid, and culturally consonant study instruments are understudies. These challenges are even more formi-
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dable when the study goals are to com-
pare health outcomes, including health
disparities across multiple ethnic and
linguistic groups. At least four steps in
the instrumentation process are partic-
ularly pertinent when conducting mul-
ticultural and health disparities research:
1) concepts to be examined must be rel-
evant across ethnic groups; 2) regula-
tion: the items that measure the
concepts are equivalent across ethnic
groups (reliability); 3) translation: the
items, as well as the instructions, must
connote the same message or meaning
across ethnic and linguistic groups; and
4) validation: the items must measure
the exact concepts across ethnic and lin-
guistic groups.

In these multiethnic studies, cultur-
ally responsive survey instruments were
developed based on previous studies
with African-American breast cancer
survivors, qualitative data obtained from
key informant and focus group in-
terviews, and the research literature.
The questionnaires were first pilot tested
with 28 breast and cervical cancer sur-
vivors representing the various ethnic
and linguistic groups. Revisions result-
ing from the pilot tests were incorpo-
rated into the final questionnaire (eg,
phrasing of questions and/or response
choices, demographic items). Marin et
al’s Short Acculturation Scale for His-
panics was adapted for use with indi-
viduals from other ethnic groups.

The final 40-page questionnaire in-
cluded standard measures of QOL (can-
cer specific, health-related, and non-
health related—life stress) and new
items generated from previous research
and the literature. Included were sub-
scases or entire standard measures
(Functional Assessment of Cancer Ther-
apy—FACT-Cx, The Life Stress
Scale, MOS-Social Support, Patient
Adherence and Quality of Care Ques-
tionnaire, Rand 36-item Health Sur-
vey). Overall, the instrument mea-
sured: 1) socioeconomic factors (eg, SES,
life stress, family functioning, social
support); 2) healthcare system issues (eg,
access, quality of care, cost); 3) cultural
factors (beliefs, language, acculturation,
spirituality); 4) demographic factors
(ethnicity, age, relationship status); 5)
medical factors (eg, stage, treatment
side-effects); 6) comorbidity; 7) health
practices; and 8) psychological well-be-
ing (eg, depression, anxiety) to assess
health disparities as well as health pro-
moters in a diverse sample of cancer
survivors. The instrument was also trans-
lated and back-translated into Spanish,
Korean, and Chinese (traditional) lan-
guages. A detailed report on this instru-
mentation is presented elsewhere.

Drawing Valid Conclusions

Results must be interpreted in the
context of appreciating all the possible
limits of the study. However, clinical
significance and translational utility of
study results are rarely discussed. In or-
der to conduct health disparities re-
search, addressing these issues is critical.
Social scientists may find qualitative
methods helpful in addressing contex-
tual issues that can inform clinical or
translational applicability. One useful
strategy is the focus group interview that
is organized to assist the investigator in
making sense of findings. Thus, the fo-
cus group held at the beginning of the
study may be used to generate new
items, while the focus group held at the
end is used to summarize the findings,
generate new hypotheses, and create rec-
ommendations for application in the
community.

For example, during focus groups in
this study, many African-American sur-
vivors presented moderate to severe
HRQOL concerns (physical, psycholog-
ical), yet their overall presentation of
their global QOL was good. The quanti-
tative study affirmed this discovery.
Significant differences between African-
American and European-American
women on the standard HRQOL sub-
scases were found; however, on the sin-
gle, self-assessed item on the overall im-
pact of breast cancer on one’s life, no
ethnic differences were seen. These re-
sults seemed to represent a discrepancy
in African-American breast cancer sur-
vivors’ evaluation of the domains of
HRQOL and their overall self-assessment
of QOL; one may then conclude
that denial is an important coping
mechanism. However, the added infor-
mation from the summative focus group
(ie, African Americans possess a world-
view that joy, as well as pain and suf-
ferring, is a normal part of life), lead
the author to conclude that the HRQOL
assessment discrepancy may be a func-
tion of cultural protective factors.

Therefore, the results of the quantita-
tive study supported the findings of the gen-
erative focus group and finally the sum-
mative focus group provided a rich,
contextual understanding of the phe-
nomenon. This process allows investig-
gators to be truly educated and in-
formed by the findings, and results in:
1) a contextually relevant interpretation
of the results and conclusion; 2) the
generation of new hypotheses and the-
oretical frameworks for future investi-
gation; and 3) the community as advi-
sors to the process and structure of ap-
plying the knowledge to benefit the
community.

Dissemination

Dissemination of the knowledge and
lessons learned is the most critical com-
ponent in developing clinical and trans-
lational utility. Typically, the scientific
and medical community is informed via
presentations and publications. Howev-
er, presenting the results to advocacy
and survivorship organizations and par-
ticipants (eg, clinically useful and simple
summary statements) is an important
step in creating clinical and translational
applicability. Community reports can
take many forms—from informal dis-
cussions at community agencies (ie, staff
and board meetings) to a community-
wide stakeholders conference. As stated
previously, multicultural studies should
include a community advisory board
with a respected voice from beginning
to end of the study. The advisory board

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cultural competency and attention to the complex issues, including sociopolitical context, cultural context, network/community context, and micro-level/personal dimensions.

**Health disparities research demands including traditionally excluded peoples**

**DISCUSSION**

Cancer control research is an important part of the commitment to reduce cancer incidence, morbidity, and mortality and to increase HRQOL. Ethnic minorities are overrepresented in cancer burden, yet underrepresented in research. Consequently, the body of knowledge concerning cancer control with ethnic minority and under-served patients is lacking. Health disparities research demands including traditionally excluded peoples and attention to the complex issues, including sociopolitical context, cultural context, network/community context, and micro-level/personal dimensions. However, within any study, the investigators have the leverage and responsibility to appropriately address investigational challenges influenced by the above contextual domains. This paper has outlined a work in progress: A Culturally Responsive Model for Research Design and its guiding principles designed to address the challenges inherent in conducting multicultural and health disparities research.

There may be limitations to this model that will be revealed as it is tested in research studies. However, one concern that may arise in the implementation of the model is the increased demand on the investigatory team to create effective community collaboration, the opportunity for cultural competency training for all research staff, and a community forum(s) for the dissemination of the findings.

Overall, the Culturally Responsive Model for Research Design appears promising. The implementation of the model facilitated the research process that recruited large numbers of African-, Asian-, Latina- and European-American breast (N=702) and cervical (N=550) cancer survivors. Investigators must appreciate and address the macro/system level and micro/individual level domains to conduct culturally responsive studies and enhance research integrity. In doing culturally responsive, multicultural research, the scientific community may begin to forge mutually beneficial relationships and collect valid data. Moreover, ethnic minority participation in health and cancer related clinical, prevention, and survivorship research may increase. The author wishes to thank Drs. A. Abernathy, M. B. Tucker, and M. Kagawa-Singer for their critical review of this manuscript.

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