

Community readiness to promote Latinas' participation in breast cancer prevention clinical trials

Catalina R. Lawsin PhD¹, Evelinn A. Borrayo PhD², Ruth Edwards PhD² and Carolina Beloso BS³

¹Department of Oncological Sciences, Mount Sinai School of Medicine, New York, New York, ²Department of Psychology, Colorado State University, Fort Collins, Colorado and ³University of Northern Colorado, Greeley, Colorado, USA

Correspondence

Catalina Lawsin
Department of Oncological Sciences
Mount Sinai School of Medicine
1425 Madison Avenue
Box 1130
New York
NY 10029
USA
E-mail: Catalina.Lawsin@mssm.edu

Requests for reprints: Evelinn A. Borrayo
PhD, Department of Psychology,
Colorado State University, Fort Collins,
Colorado 80523, USA.
E-mail: Evelinn.Borrayo@colostate.edu

Abstract

The high breast cancer (BC) mortality rates that exist among Hispanic women (Latinas) are a health disparity burden that needs to be addressed. Prevention clinical trials are a burgeoning area of cancer prevention efforts and may serve to promote parity. Unfortunately, Latinas, along with other ethnic minority women, continue to be under-represented in this form of research. Previous studies have examined individual barriers to ethnic minorities' participation, but none have assessed community factors contributing to Latinas' under-representation in these studies. The present study addressed these limitations from a community perspective by exploring which factors might inhibit Latinas' participation in clinical trials, specifically BC prevention trials. Using the Community Readiness Model (CRM), 19 key informants were interviewed in four communities, two rural and two urban, in Colorado, USA. The key informant assessment involved a semistructured interview that measured the level of community readiness to encourage participation in BC prevention activities. The results reflected a community climate that did not recognise BC as a health problem that affected Latinas in participating communities. Compared to other healthcare priorities, participation in BC prevention clinical trials was considered a low priority in these communities. Overall, leadership and community resources were not identified or allocated to encourage the participation of Latinas. The results highlight the lack of awareness regarding clinical trials among both community members and leaders. According to the CRM, strategies to enhance awareness at multiple levels in the community are necessary. This study demonstrates how the CRM can be used to better understand a community's perspective on BC, and specifically, the under-representation of Latinas in clinical trials.

Keywords: breast cancer, clinical trials, community readiness, Hispanic

Accepted for publication 12 December 2006

Introduction

The advent of improved screening technologies and treatments for breast cancer (BC) has led to an overall decrease in BC mortality in the USA (Ries *et al.* 2005). However, not all ethnic groups have demonstrated equal mortality declines. Non-Hispanic white and black

women have seen stronger improvements in mortality rates, decreasing by 13% and 7%, respectively, compared to only a 3% decrease in mortality among Hispanics (Clegg *et al.* 2002). Thus, it appears that Latinas continue to be more likely to die of BC than non-Hispanic white and black women. It is estimated that Hispanics will represent 13% of the US population (reaching 39 million

people) by the year 2010 (US Census Bureau 2001), a considerable increase from that recorded in the most recent census. Therefore, healthcare providers and researchers must be proactive in their assessment and handling of health issues when working with this population. The participation of Latinas at high risk for BC in prevention activities may be one way to promote parity in the decrease of BC mortality. At the moment, BC prevention efforts focus predominantly on selective oestrogen receptor modulators. Testing of the benefit of these chemoprevention interventions occurs via prevention clinical trials.

Clinical trials research is essential in order to determine effective medical interventions aimed at the prevention, diagnosis and treatment of illnesses. Unfortunately, participation in clinical trials research among the general population is relatively low, ranging from 3% to 20% of those eligible (National Cancer Institute 2003a,b). Participation rates are even lower among ethnic minorities. Eighty-three per cent of participants in US National Cancer Institute intramural studies are non-Hispanic white, approximately 4% are Hispanic, 2% are Asian and 10% are African American participants (National Cancer Institute Center for Cancer Research 2005). To address the under-representation of ethnic minorities, the Minority Community Clinical Oncology Program was developed in 1983 at the US National Cancer Institute (NCI). The programme was created to encourage research that focuses on understanding the barriers to minority recruitment and retention in cancer clinical trials. Despite efforts made since the advent of this programme, participation in cancer clinical trials has been particularly low among ethnic minorities (Bunn & Krebs 1999, Murthy *et al.* 2004). Moreover, although there has been a 22% increase in enrolment in NCI-sponsored treatment trials, the number of minority participants in these trials has remained constant, leading to even smaller percentages of minorities in these studies (Christian & Trimble 2003).

The most recent example of ethnic minorities' under-representation in clinical trials occurred in the Study of Tamoxifen and Raloxifene (STAR). This was a national study that was begun in 1999 in order to compare two chemoprevention therapies, tamoxifen and raloxifene, for their effectiveness in reducing the occurrence of BC among women who are at high risk. Specific strategies (e.g. ensuring community involvement in programme development and implementation) were suggested to improve the recruitment and retention of ethnic minority women into the trial (Raich & Morton 1999). Enrolment recently closed on this cancer prevention trial, and recruitment efforts resulted in 19 747 participants from more than 500 participating institutions throughout the USA, Puerto Rico and Canada (Fisher

et al. 2005). Despite intentional efforts to recruit ethnic minorities, less than 7% of participants in STAR were identified as ethnic minorities. Considering the survival benefits of participating in cancer prevention activities, the enrolment and accrual of ethnic minority participants in future clinical trials such as STAR are essential. However, Latinos continue to be disproportionately represented in clinical trials, in spite of the dramatic increase of this population living in the USA.

Previous research exploring ethnic minorities' under-representation in clinical trials has focused on individual barriers and perceived disadvantages (Ellington *et al.* 2006). For example, poor patient-provider communication (Shavers *et al.* 2002) and medical mistrust (Hussain-Gambles *et al.* 2004) because of historical mistreatment of minorities, as exemplified by the Tuskegee Syphilis Trial (Moreno-John *et al.* 2004, White 2005), have been identified as significant barriers to participation in clinical trials. While steps have been taken to ensure the ethical treatment of human subjects in research studies, other barriers to their participation remain unaddressed. Societal and institutional barriers are particularly limiting for medically underserved ethnic minority groups. Among the most salient societal barriers is their position at the bottom of the social strata, on the basis of their low socioeconomic status and literacy levels, and for some, their immigrant status as well (Freeman 1993). Institutional barriers include the fact that chemoprevention clinical trials are conducted at institutions (e.g. university hospitals and comprehensive cancer centres) in a location where women have to travel some distance to access them, and thus, participation presents logistical disadvantages. Even if such distances are relatively short, transportation and related costs become an issue for poor individuals who primarily concentrate on day-to-day survival. Borrayo *et al.* (2005) found that all of these social and institutional disadvantages contributed to the array of reservations that Latinas have about participating in BC cancer clinical trials.

Another disadvantage is the level of difficulty that women encounter in navigating the medical institution's system and procedures. An important factor that makes such tasks problematic for some Latinas is their inability to communicate in the English language. Moreover, their low health literacy also makes it difficult for them to understand the process of informed consent and the paperwork involved in clinical trials research (Borrayo *et al.* 2005). Also indisputable is the disadvantage presented by the lack of health insurance coverage among medically disadvantaged individuals. A survey conducted by the American Society of Clinical Oncology (ASCO) found that denials of reimbursement for routine patient care costs are among the main obstacles to enrolment in cancer clinical trials (Cancer Leadership

Counsel 2003). Although efforts have been implemented to facilitate access for medically underserved populations, such as Latinas, equal access to studies testing state-of-the-art BC prevention interventions continues to be a goal and a challenge.

Aim

While the understanding of individual barriers to ethnic minorities' participation in cancer clinical trials has somewhat broadened (Comis *et al.* 2003), our understanding of the community or environmental factors impacting participation continues to be very limited. The present study was conducted to investigate the problem of under-representation of Latinas in clinical trials, focusing specifically on medically underserved Latinas. Given that the existing evidence points to the low participation of Latinas in cancer clinical trials, the authors inquired about these clinical research studies within the context of discussing BC prevention and control activities in general. Using the Community Readiness Model (CRM) (Oetting *et al.* 1995), the following research questions were pursued: (1) How do Latino communities perceive BC, and what is their members' level of awareness about existent BC cancer prevention activities? (2) What is the stage of community readiness to engage Latinas in cancer prevention activities, specifically BC prevention clinical trials? (3) What are the common efforts of community leaders and community members to increase Latinas' participation in BC prevention activities, and specifically, clinical trials? The findings are discussed, and recommendations for recruitment of Latinas into BC prevention clinical trials are offered.

Theoretical framework to understand community-level factors

The CRM (Oetting *et al.* 1995) was used as a theoretical and data collection framework to guide the present study. The CRM can help to understand the factors that are likely to contribute to a community problem and to assess the readiness of its residents to engage in programmes aimed at addressing or preventing the problem, including health problems that directly affect the community (Donnermeyer *et al.* 1997, Oetting *et al.* 2001, Hussain-Gambles *et al.* 2004, Plested *et al.* 2005). The CRM has many similarities to the Transtheoretical Model (Prochaska & DiClemente 1983), but differs from it in that the CRM also helps to understand the group dynamics that can be enlisted towards solving the problem. Thus, the CRM may be useful in understanding how the problem of BC is viewed in some Latino communities. By understanding how BC is perceived and

where the community is in its efforts to address it, recommendations can be made on how to move each community towards enrolling more Latinas in clinical trials.

The CRM is a nine-stage model that is intended to determine a community's readiness to recognise and address a particular problem (see Table 1). A thorough description of the development, design and application of the CRM is found in Edwards *et al.* (2000). Briefly, each stage of readiness is defined by both a community's awareness of the pros and cons of a particular problem, and the extent to which tangible solutions can be implemented to solve or prevent the problem are considered. In addition, the CRM measures the community climate surrounding a particular issue. Included in community climate are distinct aspects of individual climate, participant climate and organisational climate. These climates have been described as 'catalysts for action' and it has been suggested that a sense of community has a catalytic effect on community action (Chavis & Wandermansman 1990, Florin *et al.* 1990). Moving from the lower stages of readiness to the higher stages of readiness, the nine stages include: no awareness; denial or resistance; vague awareness; preplanning; preparation; initiation; stabilisation; confirmation/expansion; and professionalisation (see Table 1). The CRM uses semistructured interviews including 35–40 questions that assess six dimensions that tap into a community's awareness about a problem and the existence of efforts to address it. The six dimensions in the present study included: (1) community climate and attitudes to BC as a health problem; (2) community knowledge about the issues surrounding the problem (lack of participation in BC prevention clinical trials); (3) community efforts to engage women in prevention (e.g. programmes, activities and policies); (4) community knowledge of these efforts; (5) leadership (including appointed leaders and influential community members); and (6) resources (e.g. people, monetary funding and transportation). The combined scores from all six dimensions provide an assessment of a community's readiness to recognise and take steps to address the problem at hand.

Subjects and methods

Key informants

The CRM assesses a community's level of readiness via a semistructured interview of key informants. Key informants are leaders or decision-makers in a community who work closely with the community members of interest and who can provide informed opinions regarding the problem in question. In small rural communities, leaders do not always hold formal roles, and therefore, the present authors attempted to ascertain

Table 1 Stages of community readiness

Stage	Definition	Goal
No awareness	There is no recognition of the problem by community leaders. Community climate may not recognise how behaviours foster the problem	Raise awareness
Denial/resistance	The problem is recognised, but not acknowledged to be a local problem: 'It's not our problem.' Community climate may be passive or guarded	Raise awareness of problem and how it affects the community
Vague awareness	There is recognition of the problem and that something should be done for it, but there is no immediate motivation to act. Community climate does not motivate leaders	Raise awareness that the community can help address the problem
Preplanning	There is recognition of the problem and the need to act, but there is no definite plan of how to go about doing this. Community climate is beginning to recognise the need to address the problem	Raise awareness with concrete plans to address the problem
Preparation	Planning to address the problem is in process and practical details are being discussed. Community climate offers modest support of efforts	Gather existing information to develop a concrete plan of action
Initiation	Action has been initiated to address the problem. Community climate is improved, as demonstrated by modest involvement of community members	Provide information that is tailored for the specific community
Stabilisation	Programmes are running to address the problem and have administrative support to maintain a stable status. Community climate is generally supportive of action	Stabilise efforts to address the problem
Confirmation/ expansion	Programme evaluation, and efforts to expand and fund services to other under-served areas are being conducted. Community climate may challenge changes because of increased knowledge and desire for progress, but overall it is supportive	Expand and enhance services
Professionalisation	Sophisticated data regarding the risk of the problem and the intervention that has addressed the problem are gathered. Community climate is actively involved in addressing the problem, and has the support and skills necessary to continue efforts	Maintain programmes and continue to expand

who were the key influential community leaders with and without formal roles, and then contacted them. The key informant interview is a method of assessment adopted from community psychology used to obtain objective data to determine the stage of a community's readiness to recognise and address a problem (Jumper-Thurman *et al.* 2003).

Measures

The key informant semistructured interview asked questions that tapped into the six dimensions that, together, provide an assessment of a community's readiness to address a problem. Interviews assessed each dimension using open-ended questions regarding BC prevention efforts in the community. During the time that the present study was conducted, the STAR trial was actively recruiting participants; therefore, the authors referred to this research to provide a concrete example of a cancer prevention clinical trial. Since the authors anticipated that cancer prevention clinical trials might not be well known in the community, they assessed attitudes to and awareness of BC prevention

clinical trials within the general context of participation in BC control (e.g. mammography) and prevention (e.g. chemoprevention, diet and exercise) activities. As the interviews progressed, key informants were queried more specifically about Latinas' participation in cancer clinical trials.

Procedures

Key informant interviews were conducted in two urban and two rural communities in Colorado, USA. These communities were identified as being densely populated by Latinos per capita according to the 2000 US census (US Census Bureau 2001). Contact was initiated when an interviewer telephoned community agencies to identify potential key informants and assess their leadership involvement with Latinas in the community. Once key informants agreed to participate, the interviews were conducted in either English or Spanish, depending on the preference of the key informant. Each interview lasted approximately 30–60 minutes. A total of four key informants from each community were interviewed separately. Three additional interviews were necessary

in one urban community, so as to ensure adequate coverage of a larger metropolitan city.

Data analysis

All the interviews were transcribed verbatim and those conducted in Spanish were also translated into English. Two graduate students were trained extensively in the scoring of the CRM interview. First, the interview was read prior to scoring, in order to gain a general sense or impression from the interview, and then the raters score each interview separately. The CRM scale provides specific anchored ratings for scoring each of the six dimensions, and these give a numerical score for the individual dimension. Each dimension is described with nine different statements or scales that are 'anchored' because the first and last statements describe the lowest and highest levels of readiness for that dimension, respectively. Accordingly, the first and last statements in each dimension are assigned scores of 1 and 9, respectively. The statement that best describes the content of the interview and its corresponding number is considered to be the score for that particular interview. Each dimension receives only one score. The anchored rating scales are provided for each of the CRM's six dimensions (Plested *et al.* 2005). Therefore, interviews were scored by dimensions and not by individual questions.

In the second step of the scoring process, the two raters met to discuss their individual scores and arrive at a consensus for a combined score for each of the dimensions. After both scorers agreed upon a combined score, the combined scores for each dimension across all the interviews conducted in the respective community were averaged to obtain the calculated score (see Table 2). Finally, the mean of the calculated scores (the sum of the calculated scores divided by six) was used to compute the community average score, which corresponds with a specific community stage of readiness, such that a score between a 1.0 and a 1.99 would be the first stage (no awareness), a score of 2.0–2.99 would be the second (denial/resistance), and so forth.

Results

Nineteen key informants were interviewed in the four Latino communities in Colorado to assess their perceptions of BC as a health problem for Latinas. Key informants included five community organisers, two *curanderas* (Hispanic medical practitioners), four public health nurses, two nuns, three representatives from the health department, a teacher and two community leaders working with Colorado State University's Agricultural Extension Program. The majority of the key informants were female ($n = 18$), and ranged in age from 41 to 57 years (mean = 47 years, $SD \pm 5.97$ years). Most ($n = 16$) of the key informants identified their ethnicity as Hispanic. Since all but one of the key informants had lived in the community for between 3 and 50 years (mean = 28.4 years, $SD \pm 173.3$ years), and all worked directly with community members in leadership positions, they were considered to have informed insight regarding the community's awareness of health issues of concern.

The primary focus of the interviews was to assess each community's readiness to address Latinas' BC incidence by increasing these women's participation in BC prevention activities, specifically clinical trials. The distribution of scores across these four communities illustrated generally low levels of readiness on the CRM dimensions. Although the number of CRM interviews was too small for meaningful statistical analyses between communities, the information derived is nonetheless clinically meaningful and useful. The calculated score for the six dimensions of community readiness are displayed for each community in Table 2. Using the CRM scale, three of the four communities were found to be in the 'vague awareness' stage of readiness to implement strategies to increase the under-representation of Latinas in cancer clinical trials, and specifically, cancer prevention clinical trials. Consistent with the stage of 'vague awareness', the three communities were characterised by a general sense that BC is a health problem and that something ought to be done to increase BC prevention

Table 2 Calculated scores of community readiness by dimension, followed by community average scores and stages of community readiness for each community ($n = 19$)

Dimension	Rural 1	Rural 2	Urban 1	Urban 2
Climate	4.3	5.2	5.6	4.4
Knowledge of breast cancer	3.2	3.6	4.2	3.6
Efforts	2.5	3.5	3.5	3.4
Leadership	3.0	3.4	4.1	3.6
Knowledge of efforts	3.4	3.5	3.8	3.5
Community resources	3.5	3.3	3.8	3.6
Community average scores	3.3	3.8	4.2	3.7
Community stage of readiness	Vague awareness	Vague awareness	Preplanning	Vague awareness

efforts, but there was no immediate motivation to take action in this direction. For the most part, there was no identifiable leadership from healthcare professionals or other health authorities that deal with the lack of programmes identifying Latinas at high risk for BC and recruiting these individuals as potential participants for BC prevention clinical trials.

Only one of the urban communities was at the 'preplanning' stage of addressing the lack of BC prevention programmes targeted to Latinas, specifically regarding participation in BC prevention clinical trials. Leaders in this community recognised that BC disparities exist among Latinas and that additional efforts should address this issue. In particular, there was awareness that the incidence and mortality of BC among Latinas could be lowered by participation in BC prevention interventions, such as those being currently tested in clinical trials. It was also recognised that Latinas are not fairly represented in these activities. Overall, leaders in the community at the preplanning stage were interested in increasing Latinas' participation in BC prevention and control activities, but their efforts were neither focused nor detailed. There was discussion among leaders, but no plan of action to address the problem.

Community climate

Community climate refers to the motivation of community members at large, rather than the leaders' motivation alone, to address the problem of interest (Oetting *et al.* 1995). Such common motivation is an important engine for action and change in a community. If the community climate does not recognise or favour change, any effort will not successfully affect an identifiable problem and no movement to higher stages of readiness to address the problem is possible. The climate in all four communities among Latinas was one of indifference, even in the community at the 'preplanning stage'. In other words, according to the leaders, BC was not perceived by community members as a health problem that affected Latinas in these communities. Concurrently, leaders perceived that community members did not see a need for Latinas to participate in BC clinical trials where prevention measures are being tested. A key informant in an urban setting explained:

They [community members] don't deal with it [BC] unless something crops up ... I'm sure, yeah, people think it's a problem, but it's not a problem right now because I am fine ... I've got to get to work ... but to make [a priority] the annual prevention stuff is hard.

According to key informants, community members do perceive BC as a health problem that affects them directly. Breast cancer prevention is also not seen as an

immediate need, particularly chemoprevention of BC, as tested in clinical trials. Consequently, the community members in all four communities have not approached their leaders to request that they begin to implement BC prevention efforts, and there was no perceived need to enhance awareness of BC prevention clinical trials among community members. In order for community leaders to address a particular problem, community members must actively lobby their concerns and demonstrate the need for action. One key informant explained that Latinas recognise BC as an issue that affects the community, but stated that:

Somebody should do something about it, but not me. I've heard that a lot ... Why, what, and where, but not me.

Community knowledge about breast cancer prevention and prevention clinical trials

In the three communities at the 'vague awareness' stage, community leaders perceived that Latina communities lack knowledge about and have little interest in participating in BC prevention activities, specifically clinical trials. None of the key informants knew of or were familiar with any current cancer prevention clinical trials being conducted in their or a nearby community. A key informant from a rural community who works with many Latino migrant workers suggested that transient lifestyles probably inhibit this population from knowing about or accessing health programmes:

I'm not sure they [migrant workers] would be aware of all these efforts ... [but] they're not in one place long enough to follow through or have a primary care physician.

One key informant from the community in the 'preplanning stage' stated:

This little bit of prevention [e.g. exercise and diet as a means of reducing BC risk] that there is out there, it's not known by everybody that can access it.

Community efforts to engage women in prevention programmes

According to the key informants' from communities at the 'vague awareness' stage, healthcare providers have made little or no effort to engage women in BC prevention activities, specifically to recruit women into BC prevention clinical trials. Key informants from the rural and the urban communities cited several initiatives to increase participation in BC control activities (e.g. free mammography screening); however, when asked about prevention activities, such as those tested in clinical trials, they could not recall any ongoing activities in their communities. Key informants identified several barriers to

engaging women in BC control activities, such as lack of time, transportation, and childcare, that inhibit women from participating. Similar barriers were also expected to impede Latinas' participation in BC prevention clinical trials. In the urban community at the 'preplanning' stage, efforts among healthcare workers have also mostly focused on BC control. Although there has been a discussion regarding the existence of BC prevention interventions, such as chemoprevention or prophylactic mastectomy, no real planning for these activities has begun.

Leadership

No key informant identified any leaders at the state or federal government level assigned to systematically address the lack of Latinas' participation in BC prevention activities, including participation in BC prevention clinical trials, and thus, community leaders have not been motivated to deal with this problem. A key informant working with the health department in a rural community stated:

I'm not sure that they've [leaders] really gone into specifically BC prevention. And it's probably just because they haven't really thought about it ... not intentionally that they don't want to do anything about it.

Several key informants identified other health-related issues (e.g. health insurance coverage) as higher priorities in these low-income Latino communities. Therefore, little focus has been placed on preventive health, and particularly, on BC prevention activities, such as those tested in clinical trials.

The urban community at the 'preplanning stage' had identifiable leaders working with BC issues. In this community, leaders meet regularly to discuss enhancement of BC control activities (e.g. providing free mammogram screenings each month, and funding for BC treatment for lower-income individuals), but there were no identifiable leaders in the area of BC prevention. Although there were no leaders responsible for recruitment into clinical trials, some had made efforts to increase exercise and decrease smoking as means of cancer prevention. However, these efforts were not specifically aimed at prevention of BC.

Community knowledge of efforts to increase breast cancer prevention

In all four communities, key informants believed that Latinas were familiar with BC as an illness that typically affects women. However, despite education efforts, many of these Latinas still lack adequate understanding of the causes, symptoms, treatment and prevention

interventions available for individuals at high risk for BC. When asked what community members knew about BC, key informants reported that Latinas often had many misconceptions. Latinas not only had minimal knowledge regarding BC in general, but their knowledge regarding BC prevention efforts, specifically chemoprevention interventions tested in clinical trials, was almost nonexistent.

Community resources

Insufficient resources were reported to be available to address BC prevention in the four communities. Although all key informants perceived that community members would be supportive of prevention efforts, they thought that tangible resources, such as time and money, were lacking. For example, when asked what the community offers to support BC activities, a key informant from a rural community stated:

Both money and space are very tight. So, um, I mean people probably are willing to help with a good cause, but at the same time, their hands may be tied. Because everywhere the space may be very limited and it is hard to come by the funds. Since there have been so many cutbacks lately in funding, that also is a problem. So it is not necessarily that these people are unwilling to help, it is that they are unable to.

In the urban city at the 'preplanning stage', space was not perceived to be a barrier. As one key informant stated, 'Space, uh, I think community agencies have been pretty helpful with space, if we really needed it.' She further explained that churches and community centres are often willing to donate space for educational seminars or health fairs. She cited that Latino radio stations will often publicise programmes or special events in the community free of charge, but other advertising community services (e.g. TV advertising) are often expensive for community agencies to use. Alternative strategies to promote health activities include announcements in church bulletins and booths at cultural events. However, this key informant added that other resources, specifically work force, are often lacking when there is a need to organise educational programmes and recruit participants. Key informants from all the communities were unaware of any grants or funding opportunities to initiate BC prevention programmes directed towards educating community members about BC prevention clinical trials, and no plans have been made to seek out funding.

Discussion

Through key informant interviews, the CRM proved to be an effective theoretical and data collection method

for assessing the community level factors that are likely to impact Latinas' participation in BC prevention clinical trials. Moreover, the CRM helped to formulate the suggestions that the present authors offer in this section regarding possible interventions that can be implemented to move communities to a higher stage of readiness to encourage Latinas' participation in clinical trials. Overall, the results suggest that there were no real differences between rural and urban communities in their recognition of BC as a health problem that affects Latinas, nor were there differences in regard to the existence of intervention programmes to encourage their participation in BC prevention clinical trials.

The present authors found that three of the four communities assessed were in the 'vague awareness' stage of community readiness, and according to key informants, community members had minimal knowledge regarding the significance of BC prevention efforts, specifically efforts necessary to recruit Latinas into BC prevention clinical trials. It was also apparent that the key informants, even in the community in the 'preplanning' stage, had never been approached by a representative of a clinical trial to identify Latinas who may be at high risk for BC or recruit potential participants. When the authors assessed the climate in the four target communities, it was not surprising that the perceived climate of indifference towards the need to prevent BC in each community paralleled the community's low level of readiness towards alleviating BC health disparities that exist for Latinas. These results point to the need for multilevel interventions within each community. For communities in the 'vague awareness' stage, the primary goal is to heighten awareness at all levels (e.g. government, and community leaders and members) of the importance of reducing disparities in BC for Latinas, an ethnic group with relatively high mortality rates from BC (Plested *et al.* 2005).

In general, existing efforts in the four communities were organised around BC control activities (e.g. mammograms and clinical breast exams), rather than BC prevention activities, such as those tested in clinical trials. Interventions to improve recruitment of Latinas in communities similar to those in the present study need to facilitate the organisation of community groups to begin grassroots efforts to target Latinas at high risk for BC as potential participants for prevention clinical trials and to enhance recruitment efforts. Amid these groups, clinical trial coordinators may benefit from working with key leaders in the community to effectively guide their interventions. In addition, leaders in charge of implementing recruitment interventions could build upon previous successful health promotion programmes (e.g. free mammogram screening) to begin to heighten awareness of the existence of BC prevention clinical

trials. They also need to educate their community about how the participation of women at high risk for BC may reduce the likelihood that they would acquire the illness. These efforts should be implemented in clinical trial recruitment plans to provide the necessary financial support for recruiters to successfully enter the Latino communities and work with key influential leaders.

Previous research has demonstrated that more individuals are eligible to participate in clinical trials than those who are actually recruited (Comis *et al.* 2003). One step in recruiting for BC prevention clinical trials is to identify individuals who are at high risk for BC and potential candidates for these studies. For example, having a family history of cancer is one of the eligibility criteria to participate in cancer chemoprevention clinical trials (Cauley *et al.* 2001, Fisher *et al.* 2005). Another step would be to better educate leaders and the community at large about the risks of BC, and the advantages and disadvantages of participating in BC prevention clinical trials for individuals at high risk of acquiring the illness. Recruitment efforts that increase awareness about the location of the clinical trials (e.g. university hospitals and community clinics) are also likely to improve enrolment. Furthermore, key informants reported that community members would probably be willing to offer their time, and if necessary, their homes to contribute to health promotion efforts; however, they are likely to be unaware of the need for their assistance. Collaborative relationships between community members, leaders and researchers have fostered the success of community health promotion programmes in the past. Thus, clinical trial studies should involve community members and leaders in the accrual and retention of ethnic minority women, such as Latinas, into cancer prevention clinical trials.

Another important issue raised by key informants was that healthcare providers did not prioritise BC prevention amid the numerous health issues that are currently problematic in their communities. The medical community is already experiencing difficulty providing primary medical care to uninsured Latinas; therefore, involving them in clinical trials might be seen as an unaffordable expense. Clinical trials personnel should consider the logistical and financial barriers when designing recruitment protocols and approaching community leaders for their assistance. A survey conducted by ASCO found that denials of reimbursement for routine patient care costs are among the main obstacles to enrolment in cancer clinical trials (Cancer Leadership Counsel 2003). Routine patient care costs include physician charges, hospital charges and routine tests. Changes in public policy since 2000 have increasingly mandated third-party payers, including Medicare, to cover routine patient care costs associated with clinical

trials. Although prevention cancer clinical trials are not automatically covered, they can be covered if they are certified to meet a set of qualifying criteria (National Cancer Institute 2002, 2003a,b).

Barriers inherent in the clinical trial protocol may discourage the inclusion of ethnic minorities in BC prevention clinical trials. For example, Grann *et al.* (2005) examined how the racial, socioeconomic and Gail Model risk factors impacted on participation among 847 individuals who expressed interest in participating in the STAR trial. The above authors found that, after adjusting for race/ethnicity and socioeconomic factors, many ethnic minorities were still ineligible to participate in the STAR trial. Other barriers are inherent in the distant location where clinical trials are conducted. For example, of the four Colorado communities included in the present study, only the large urban centre had a hospital that was recruiting women into the STAR trial. Key informants may not be aware of the opportunity to enrol community members if they are geographically distant from the location where the study is being conducted.

Limitations and future directions

A limitation of using the CRM is that it may neglect a variety of factors that contribute to Latinas' underrepresentation in clinical trials that extend beyond the six dimensions assessed during key informant interviews. Factors not assessed by the CRM may include the influence of being from a lower socioeconomic background, being female or being a minority. Another limitation of the CRM is the reliance on key informants, given that their views may represent only the vocal majority as opposed to the community at large. Beebe *et al.* (2001) argued that key informants might use their responses to meet a particular political objective. To overcome this shortcoming, the present authors interviewed a wide range of representatives in the four communities, from individuals from the health department and non-profit organisations to independent folk healers. By interviewing leaders who work with community members on a variety of levels, the authors attempted to gain perspectives that would represent different factions in the community.

The present study contributes to the literature by providing some initial direction for future studies interested in understanding how community components influence Latinas' participation in BC prevention clinical trials. Future research may benefit from expanding upon this study by applying the CRM to additional areas of BC prevention and control, or by exploring the feasibility of implementing intervention recommendations based on the CRM. Because the study only used

key informants, additional research needs to be conducted with Latinas already participating in a BC prevention clinical trial to learn about factors that contribute to retention in clinical trials. Unfortunately, Latinas' marked absence in clinical trials makes this very difficult. As we become more successful in enrolling Latinas into clinical trials, we can better understand the mechanisms required to enhance care among all ethnicities, and promote parity in cancer treatment and recovery.

Acknowledgements

This project was funded with a 2001 grant from the Denver Metropolitan Affiliate of the Susan G. Komen Breast Cancer Foundation, Denver, CO, USA. The writing of this paper was supported by Grant No. NCI-CA81137-05 from the National Cancer Institute.

References

- Beebe T.J., Harrison P.A., Sharma A. & Hedger S. (2001) The community readiness survey. Development and initial validation. *Evaluation Review* 25 (1), 55–71.
- Borrayo E., Lawsin C. & Coit C. (2005) Latinas' appraisal of enrollment and adherence to breast cancer prevention trials. *Cancer Control Cancer, Culture and Literacy Suppl.*, 107–110.
- Bunn P. & Krebs L. (1997) *Colorado Blueprint: Women and Minorities in Cancer Care Trials*. University of Colorado Comprehensive Cancer Center, Denver, CO.
- Cancer Leadership Council (2000) *Clinical Trials Coverage*. 12-16-2003a.
- Cauley J.A., Norton L., Lippman M.E., *et al.* (2001) Continued breast cancer risk reduction in postmenopausal women treated with raloxifene: 4-year results from the MORE trial. Multiple outcomes of raloxifene intervention. *Breast Cancer Research and Treatment* 65, 125–134.
- Chavis D.M. & Wandermansman A. (1990) Sense of community in the urban environment: a catalyst for participation and community development. *American Journal of Community Psychology* 18 (1), 55–81.
- Christian M.C. & Trimble E.L. (2003) Increasing participation of physicians and patients from underrepresented racial and ethnic groups in National Cancer Institute-sponsored clinical trials. *Cancer Epidemiology, Biomarkers and Prevention* 12 (3), 277–283.
- Clegg L.X., Li F.P., Hankey B.F., Chu K. & Edwards B.K. (2002) Cancer survival among US Whites and minorities. *Archives of Internal Medicine* 162, 1985–1993.
- Comis R.L., Miller J.D., Aldige C.R., Krebs L. & Stoval E. (2003) Public attitudes toward participation in cancer clinical trials. *Journal of Clinical Oncology* 21 (5), 830–835.
- Donnermeyer J.F., Oetting E.R., Plested B.A., Edwards R.W., Jumper-Thurman P. & Littlethunder L. (1997) Community readiness and prevention programs. *Journal of Community Development* 28 (1), 65–83.
- Edwards R.W., Jumper-Thurman P., Plested P.A., Oetting E.R. & Swanson L. (2000) Community readiness: research to practice. *Journal of Community Psychology* 28 (3), 291–307.
- Ellington L.W.S., Martin S.S., Field R. & Mooney K. (2006) Factors that influence Spanish- and English-speaking

- participants' decision to enroll in cancer randomized clinical trials. *Psycho-Oncology* 15, 273–284.
- Fisher B., Costantino J.P., Wickerham D.L., *et al.* (2005) Tamoxifen for the prevention of breast cancer: current status of the National Surgical Adjuvant Breast and Bowel Project P-1 Study. *Journal of the National Cancer Institute* 97 (22), 1652–1662.
- Florin P., Giamartino G.A., Kenny D.A. & Wansersman A. (1990) Levels of analysis and effects: clarifying group influence and climate by separating individual and group effects. *Journal of Applied and Social Psychology* 20 (11), 881–900.
- Freeman H.P. (1993) The impact of clinical trials protocols on patient care systems in a large city hospital: access for the socially disadvantaged. *Cancer* 72 (9), 2834–2838.
- Grann V.R., Jacobson J.S., Troxel A.B., Hershman D., Karp J., Myers C. & Neugut A.I. (2005) Barriers to minority participation in breast carcinoma prevention trials. *Cancer* 104 (2), 374–379.
- Hussain-Gambles M., Atkin K. & Leese B. (2004) Why ethnic minority groups are under-represented in clinical trials: a review of the literature. *Health and Social Care in the Community* 12 (5), 382–388.
- Jumper-Thurman P., Edwards R.W., Plested B.A. & Oetting E.R. (2003) Honoring the differences: using community readiness to create culturally valid community interventions. In: G. Bernal, J. E. Trimble, A. K. Burlew & F. T. L. Leong (Eds) *Handbook of Racial and Ethnic Minority Psychology*, pp. 591–607. Sage, Thousand Oaks, CA.
- Moreno-John G., Gachie A., Fleming C.M., Napoles-Springer A., Mutran E., Manson S.M. & Perez-Stable E.J. (2004) Ethnic minority older adults participating in clinical research: developing trust. *Journal of Aging and Health* 16 (Suppl. 5), 93S–123S.
- Murthy V.H., Krumholz H.M. & Gross C.P. (2004) Participation in cancer clinical trials: race-, sex-, and age-based disparities. *Journal of the American Medical Association* 291 (22), 2720–2726.
- National Cancer Institute (2002) *Medicare Coverage of Clinical Trials*. December 16, 2003. National Cancer Institute, Bethesda, MD.
- National Cancer Institute (2003a) *Decades of Progress: 1983–2003. Community Clinical Oncology Program*. National Cancer Institute, Bethesda, MD.
- National Cancer Institute (2003b) *Physician Data Query*. [WWW document.] URL <http://www.cancer.gov/cancertopics/pdq/cancerdatabase> (accessed August 5, 2006).
- National Cancer Institute (2005) *Center for Cancer Research*. National Cancer Institute, Bethesda, MD.
- Oetting E.R., Donnermeyer J.F., Plested B.A., Edwards R.W., Kelly K. & Beauvais F. (1995) Assessing community readiness for prevention. *International Journal of Addiction* 30 (6), 659–683.
- Oetting E.R., Jumper-Thurman P., Plested B.A. & Edwards B.K. (2001) Community readiness and health services. *Substance Use and Misuse* 36 (6 & 7), 825–843.
- Plested B.A., Jumper-Thurman P., Edwards R.W. & Oetting E.R. (2005) Community readiness: a tool for effective community-based prevention. *Prevention Researcher* 5 (2), 5–7.
- Prochaska J.O. & DiClemente C.C. (1983) Stages and processes of self-change in smoking: toward an integrative model of change. *Journal of Consulting and Clinical Psychology* 5, 390–395.
- Raich P. & Morton N. (1999) A new cancer education mission: managed care and clinical trials. *Journal of Cancer Education* 14 (2), 93–95.
- Ries L.A.G., Eisner M.P., Kosary C.L., *et al.* (Eds) (2005) *SEER Cancer Statistics Review, 1975–2002*. National Cancer Institute, Bethesda, MD.
- Shavers V.L., Lynch C.F. & Burmeister L.F. (2002) Racial differences in factors that influence the willingness to participate in medical research studies. *Annals of Epidemiology* 12 (4), 248–256.
- US Census Bureau (2001) *Population by Race and Hispanic or Latino Origin, for All Ages and for 18 Years and Over, for the United States: 2000*. US Census Bureau, Washington, DC.
- White R.M. (2005) Misinformation and misbeliefs in the Tuskegee Study of Untreated Syphilis fuel mistrust in the healthcare system. *Journal of the National Medical Association* 97 (11), 1566–1573.