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Conducting a formative evaluation of an intervention promoting mammography screening in an American Indian community: The Native Women's Health Project.

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Abstract

Background: Breast cancer is an important public health issue among American Indian/Alaska Native (AI/AN) women. However, there are very few published studies describing the evaluation of breast health promotion programs among AI/AN women.

Purpose: To describe the formative evaluation of a multi-component intervention to promote mammography screening in an AI community in rural Oklahoma.

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Conflict of interest statement

There is no conflict of interest to disclose.

Methods: A comprehensive process evaluation plan with emphasis on context, reach, dose received, dose delivered, and fidelity was developed. Data collection included mixed research methodology and impact was assessed via one group pre/post research design. Data analysis consisted of descriptive statistical analysis and content analysis. The study utilized a community-based participatory research (CBPR) approach.

Results: Process evaluation revealed a relatively high reach within the priority population for both components (clinic and community) and a moderate implementation. Focus group research showed that participants were overall satisfied with program implementation. The intervention was feasible to implement in real-world settings.

Translation to health education practice: Community-based evaluation of breast health promotion programs among AI communities is challenging, as one has to balance methodological rigor with practical constraints. The use of an evaluation plan, mixed methods and a collaborative approach are useful tools in conducting the evaluation.

Keywords

American Indian/Alaska Native; Mammography; Theory of Planned Behavior; Evaluation; Community

INTRODUCTION

Breast cancer continues to be a major public health issue among American Indian/Alaska Native (AI/AN) women in the United States (US).¹ AI/AN women are more likely to be diagnosed with late-stage breast cancer² and with a more aggressive form of breast cancer.³ In Oklahoma, where the study took place, the incidence rate of breast cancer among AI/AN women was 140.5/100,000 compared to 121.5/100,000 among Non-Hispanic White women for 2007–2009.⁴ Based on a more recent study, AI/AN and White women in Oklahoma had similar 5 year observed survival rates (79.4 % and 80.2%, respectively), however, within the 40–49 year old group, the survival rates were significantly lower among AI/ANs ($p < 0.0001$) (70 % and 63.8 % respectively).⁵ Moreover, among AI/AN women the mammography screening rate is low, 55% in 2017⁶ and 53% in 2015⁷, which was in fact the lowest among all racial/ethnic groups.

Despite the intense efforts to promote mammography screening in Oklahoma there are still geographical disparities among AI communities in terms of breast cancer mortality, incidence, and stage diagnosis.⁸ One way to eliminate disparities is by building local health promotion programs that address the specific needs of the communities they serve.

Literature reveals a limited number of published articles on community-based breast health promotion interventions within the AI/AN community.^{9–17} Among these programs only a few^{11,16,17} describe in detail the evaluation of the interventions.

A study by English et al (2008)¹¹ evaluated a multi-component intervention through tribal participatory approach. All women who participated in the study got a mammogram. The study produced community related outcomes, such as the development of a partnership between the tribe and external partners, development of local policy initiatives to address

cancer in the community and reinforcement of public health skills among community health providers.

Strickland and colleagues¹⁶ conducted a feasibility study of a multi-component intervention which included an educational program, recommendation by a tribal medical provider to get screening mammography, and a follow-up reinforcement with the use of phone calls, cards and home visits. The focus of the study was mostly on the quality of the implementation of the intervention and included the use of tracking logs and interviews, a survey administration and field observations. The study showed that the intervention was feasible.

Finally, a study by Friederichs-Fitzwater and colleagues¹⁷ evaluated an educational workshop that focused on the enhancement of knowledge, attitudes, and intentions to change lifestyle and screening behaviors. The evaluation design used was a one-group pretest-posttest. The evaluation showed that the participants at the end of the intervention had an increased knowledge about breast cancer and more positive attitudes towards mammography.

One can observe from the above studies that none incorporated an advanced evaluation design. This is not surprising. Historically, the use of an experimental design assessing the impact of an intervention among AI/AN communities, is generally discouraged for ethical and practical reasons.¹⁸ There are also challenges in doing comparative research among tribal communities because of varying tribal histories, locations, resources, and sizes. Nevertheless, despite these challenges, evaluators recently were able to incorporate more complex evaluation designs besides one group pre and post in the evaluation of programs related to the prevention of alcohol and drug abuse,¹⁹ promotion of HPV vaccination,²⁰ and prevention of obesity.²¹

Research also shows that there is a lack of evidence-based behavioral studies conducted in real-world settings.²² Evidence-based recommendations for behavioral interventions are the result of highly controlled efficacy trials which although they have high internal validity, they have low generalizability. In other words, the interventions might not be applicable in real-world settings. Feasibility studies are useful in helping fill this important gap in the research literature.²³ To ensure that feasibility studies reflect the reality of community it is essential that practitioners and community members be involved in meaningful ways on the design and implementation of study.²³ One way to do that is by using Community-Based Participatory Research (CBPR).²⁴

In summary, there are very few published evaluation studies of evidence-based behavioral interventions promoting mammography screening among AI/AN women, even though in recent years there is more emphasis on the evaluation of health promotion programs among AI communities. More importantly, there are even fewer studies that have incorporated a holistic approach to evaluation that includes process evaluation, and impact evaluation with emphasis on different outcomes besides knowledge.^{11,16}

This study attempted to fill this research gap. The article describes the formative evaluation of a culturally appropriate intervention promoting mammography screening called the *Native Women's Health Project* (NWHP).¹⁵ Culturally appropriate interventions are those

interventions that emerge from the community's traditions, values, and capitalize on strengths and resources of the community.¹⁸ In formative evaluation, there is a heavy emphasis on process evaluation while assessing early impact of the intervention.²⁵ Therefore, the study's research questions focused first on the intervention's feasibility, "Can the intervention work?", and second on its immediate impact that is "Does it work in terms of promoting mammography screening" and if yes, "why"?

PURPOSE

For tribal programs to be successful and effective, they need to be evaluated within their own context.¹⁸ Information derived from the evaluation can help program planners find out what worked or did not work in terms of program implementation, revise accordingly, improve and reimplement. Therefore, the purpose of this paper is to use the evaluation of the NWHP as a case study to showcase how an innovative, new program on mammography screening can be evaluated by using a comprehensive approach and through CBPR.²⁴

METHODS

Planning of an evaluation is equally important as its implementation. Evaluation planning in this study included the development of the theory of change (Figure 1), a Logic Model, the use of a Community Steering Committee (CSC), and the development of a process evaluation plan.¹⁸

The theory of change was based on the Theory of Planned Behavior^{26,27} and it was the outcome of years of formative research in the community.^{28,29} According to the theory of change, AI women who communicate with their medical provider on mammography screening, participate in a related discussion group and receive a bracelet as a congratulatory gift, are more likely to intend or decide to get a mammogram and subsequently get a mammogram.

The CSC provided the structure through which community members were actively involved and guided the research process, so that the investigators assured that the process was responsive and respectful to the communities.³⁰ The CSC consisted of lay people in the community, breast cancer survivors, tribal clinic representatives, and representatives of other local coalitions and other state organizations.

The process evaluation plan depicted how each component of the intervention would be evaluated and by whom. The evaluation research design consisted of a one-group pretest-posttest design. Upon entry in the study the research participants would complete a baseline evaluation survey and they would receive the post-evaluation survey after 3–5 months' post-baseline measurement. Formative evaluation was carried out by incorporating a mixed research methodology and by using CBPR.²⁴

Description of the intervention

The NWHP¹⁵ took place at a tribal clinic and its surrounding Native American community south east of Oklahoma City. This 4-year study is a continuation of two preliminary

studies^{28,29} which led to the development of the intervention. During the first study²⁸ we identified the salient beliefs regarding screening mammography among AI/AN women and during the second study²⁹ we measured the strength of each belief through a cross-sectional study. The results were used to plan the intervention¹⁵ by using the CBPR approach.²⁴

The intervention focused on promoting systems change at the local tribal clinic as well as at the broader community. The clinic-based component included the following strategies: a) A patient-doctor guided communication on mammography screening; b) The delivery and subsequent discussion with the patient of a mammography brochure developed specifically for this project;³¹ c) A follow-up recommendation letter on mammography screening sent to the patient by the physician; d) The use of a mammography screening flowchart that assisted the clinic's physicians when advising patients on mammography screening; and e) The development of a bulletin board poster at the clinic that encourages women to get a screening mammogram.

The mammography brochure was designed based on the 6-page letter fold template and comprised of 573 words. It contained information on basic scientific facts about breast cancer and mammography, including survivorship, and a testimonial from an AI breast cancer survivor who was also a member of the CSC. The purpose of the brochure was to enhance awareness of the importance of breast cancer screening among AI/AN women and to assist the medical providers during their communication with the patient on breast cancer screening. The reading level of the brochure is at the ninth grade level based on the SMOG readability formula. More information about the development of the brochure can be found in a previous publication.³¹

The community-based component included the following: a) Participation to a related discussion group called the Inter-Generational Discussion Group (IGDG) accompanied by a younger female relative, preferably a daughter, or friend; and b) Provision of a congratulatory gift (i.e. a bracelet) upon receiving a screening mammogram.

At the entry point of the intervention, the participant filled out a form called the decision-stage form which she then gave to the medical provider. The medical provider then discussed the topic of mammography screening with the patient according to the decision stage she was in, based on the Precaution Adoption Process Model.³² For instance, if the patient had never heard of screening mammogram (stage 1) then the content of the medical provider's conversation would focus on providing basic information on pros and cons of screening mammography. On the other hand, if the patient had heard of screening mammogram and was considering getting one (stage 3), then the conversation would focus on discussing the logistics of scheduling a mammogram and identifying possible barriers and solutions to attend the mammogram. Within a week of the visit, a clinic administrator would send a letter to the participant recommending mammography screening. Within a month of the visit, the participant was invited to an IGDG.

During the IGDG the research participants watched a 10-minute excerpt from a video called *The Pink Shawl Project*, which is a project that depicted AI breast cancer survivors who made pink shawls and gave them as gifts to their daughters. The shawls in the AI culture

signify protection and care of the children by their mothers. The video conveyed the importance of regular mammography screening, and passing these important preventative breast health messages as an act of care and love from the older generation of AI women to the younger generation, the same way a mother would give to her daughter a pink shawl. Based on the Freire philosophy of raising consciousness^{33,34} the excerpt acted as a “code” that triggered a structured discussion around the issue of breast cancer. The discussion was facilitated by the project coordinator (CT) and all the participants were sited in a circle. The discussion started by first reflecting on the broader AI community’s status and relationship with breast cancer, then moved to a personal level where women discussed how breast cancer affected their personal lives, and ended with a menu of action steps suggested by the women themselves. The IGDG lasted for approximately 90 minutes, and it was scheduled monthly. Besides the above discussion, it included story telling through singing by a breast cancer survivor, and other educational interactive fun activities such as the palpation of a breast model with irregular masses. More information about the IGDG can be found elsewhere.¹⁵

The intervention program was launched in June 2014 and lasted until December 2014. However, the actual participation in the intervention by the participant (meeting with the medical provider and participation at the IGDG) only took a few hours. It is also important to note that during the implementation of the intervention there was a change in leadership of the clinic’s administration.

Recruitment

A detailed recruitment protocol was developed and only active patients from the clinic were enrolled to the study. Active patients were defined as those patients who have used the clinic’s services at least once during the last two years. An invitation to the program signed by the clinic director was sent by mail to each potential participant. Within a week of mailing out the invitations, the project coordinator (CT) would call each participant to find out if they have received the letter and if they were interested in the study. The eligibility criteria for the study participation were: a) Being American Indian; b) Ages between 52–74 years old; c) No history of breast cancer; d) Not having had a mammogram during the last 2 years or more; and d) The patient must have had at the time of the recruitment a pre-scheduled visit to the clinic within the following month. All women who participated in the intervention were also eligible to participate in the evaluation portion of the intervention.

The recruitment process was monitored on a monthly basis with the help of a flow-chart that depicted the number of women who were contacted, among those who were potentially eligible to be in the study, the number of women who were truly eligible for the study and the number of women who were actually interviewed. Despite our efforts to contact the potential participants and recruit them to the study the overall response rate was 59%. The moderate response rate was due primarily to the fact we were not able to contact many of the participants either due to outdated contact information or just being unable to reach them via phone.

Process evaluation and Process evaluation plan

All staff members hired for the project were local AI women. As part of the CBPR process the first author (ET) conducted various training sessions with the staff, project coordinator and Community Research Assistants (CRAs), on data collection. The staff and members of the CSC also received a training in CBPR by two experts in the field and collaborators on this project. An approval by the tribal authority in the form of a tribal resolution was obtained and maintained during the project. All staff members received an ethics-related training via the University of Oklahoma Health Sciences Center Institutional Review Board.

A comprehensive process evaluation plan was developed to assist with the implementation of the evaluation. This evaluation plan was guided by the framework developed by Steckler and Linnann.³⁵ It consisted of a table that included the intervention component that would be evaluated (e.g. Mammography brochure), the questions to be answered according to the main dimensions of process evaluation (e.g. reach, dosage delivered, dosage received, fidelity), and the measures that would provide the information needed to answer the questions (e.g. physician log, discussion with physicians at the end of the study) (Table 1).

A secondary evaluation planning framework used was the “Plan, Do, Study, Act” (PDSA) change cycle.^{36,37} The PDSA cycle is an iterative process where a task is first introduced at a small scale, then is evaluated by those who actually carried out the task, and then based on the assessment, modify the task and start a new cycle. As one moves through the cycle, the task is tested at a larger scale.

Evaluation Survey

The evaluation survey was a modification of the Women’s Health Survey used earlier in the study to assess the AI/AN women’s beliefs on screening mammogram.²⁹ This survey included the constructs/scales which the intervention intended to address such as social modeling, social norms, fatalistic attitudes and knowledge on mammography screening. It also measured the two most important outcomes of the intervention, that is the intention of getting a future mammogram within the next 3–5 months, and the actual mammography behavior.

The behavioral variable was defined as a composite outcome including the women who had the mammogram at the time of the post-survey and women who had a mammogram reported during the follow-up call within the 6 months after the end of the intervention. The intention variable was measured with the question “How likely is it that you will obtain your next mammogram within the next 3–5 months (coded as a five-point scale from very unlikely to very likely)?

There were two versions of the survey: the pre and the post-evaluation survey. They were exactly the same with only a few additional questions on the post-evaluation survey. The post-evaluation survey included process evaluation related questions such as whether the participant received or not the mammography brochure, it was 15 pages long, and included 105 items. The average time for the completion of the survey was twenty minutes and it was self-administered. However, a member of the research team was nearby to assist with any questions the participant might have.

Quantitative data analysis

Descriptive statistics were calculated, followed by the completion of univariate and bivariate analysis comparing the mean scores of the quantitative measures (attitude, self-efficacy, social norms, perceived control, breast cancer fatalism) between those who received a mammogram and those who did not during the follow-up period. Data analysis was focused on the 21 participants who completed both the pre and post-surveys among the 29 who participated in the project.

Because of the small sample size, nonparametric methods were used, including a Wilcoxon rank sum test to compare median values between independent groups. Fisher's exact test was used to compare proportions between independent groups and an exact form of the Cochran-Armitage test for trend was used to compare the distribution of ordered, categorical responses between independent groups. Multivariate modeling, with adjustment for confounding factors, was not feasible. A two-sided alpha level of 0.05 was used to define statistical significance for the analysis. The data were entered by the Graduate Research Assistant (GRA) and every entry of the record was double-checked either by a different GRA or by the first author (ET). The data were cleaned before the data analysis.

Qualitative research

The quality of the program was also assessed through focus group research and an interview with the medical director of the entire health system of the tribe. We invited all women who have participated in the clinic and community-based components of the intervention regardless of their intention or behavioral background (i.e. whether they received a mammogram or not). Among the 17 women who were eligible to participate only 4 actually accepted our invitation. Two focus groups were conducted five months upon the completion of the project. They were conducted by the first author (ET) with the help of the CRA who was the assistant moderator/note-taker. Each interview lasted for about 60 minutes. The note-taker was trained by the PI on how to take notes during a focus group discussion. Member checking was done at the end of each focus group by having the note-taker summarize the information collected during the focus group and confirm with the participants that the information collected accurately reflected what was said in the group. The content analysis was done with the help of two trained in qualitative research graduate students and according to standard guidelines.³⁸ Each researcher first identified the main ideas/themes individually and then the group came together to discuss their findings and derive to conclusions. A theme was defined as an idea/belief noted in both focus groups that were completed. Due to the small number of participants and focus groups, we felt that we did not reach data saturation. However, the information gained from the focus group was still valuable in the evaluation of the NWHP.

RESULTS

Process evaluation

Process evaluation centered on ensuring the quality of the two intervention components; the clinic-based component (patient-doctor guided communication, recommendation for mammography letter, screening flowchart, and delivery of mammography brochure) and the

community-based component (IGDGs and the receipt of a bracelet as a congratulatory gift upon receiving a screening mammogram).

All women participated in the guided communication with the medical provider, however, only 17 out of 21 (80%) attended the IGDG. In regards to the clinic-based component, only twelve women, indicated that their medical provider discussed with them mammography screening, and 13 out of the 21 said that they had the opportunity to ask her/him questions about mammography screening. Eighteen women said that they received the mammography brochure; six women noted that they received the mammography brochure via mail, three during their visit with the medical provider, and nine during the IGDG they had participated in. When asked to write down what they remembered from reading the brochure seven women said the importance of mammography as a breast cancer early detection tool, one woman wrote “truths and myths about breast cancer”, two women said “nothing” and one woman “I don’t remember.” Twelve out of twenty women (one person did not answer this question) said that they have not received the physician’s mammography recommendation letter in the mail. In addition, logs were prepared and given to the medical providers to complete at the end of each visit with the patient. Among the 29 participants who entered the study, we received only 9 logs. We also received 14 copies of the decision stage forms. Finally, we only received five copies of the recommendation letter sent by the medical provider to the patient.

In regards to the community-based component, we conducted six IGDGs. Seventeen out of the 21 research participants participated in them, but only half of them brought a younger female guest. Based on our facilitator check-list, all topic/activities were fully implemented with the exception of the survivor’s story that was to be delivered by one of our volunteers. Overall, based on the evaluations the participants completed at the end of each session, the participants enjoyed the IGDGs. All participants rated both the discussion group and the facilitator as “excellent”. In terms of knowledge gained, the participants commented on the importance of being familiar with one’s body, of regular mammography, and of support groups. They also acknowledged the pervasiveness of breast cancer across ages and races, and that they would share information they received through the NWHF with their family members and friends.

Additional information that we received from the post evaluation survey revealed that 13 women out of the 18 who answered the related question, stated that they have read the bulletin board poster on mammography screening at the clinic. When asked at which point the women decided to get a screening mammogram six out of the 15 women who answered this question said it was after they have completed the pre-evaluation survey, three after talking to the medical provider, three after participating in the discussion group, one after receiving the physician recommendation letter, and two after finding out that the local tribal clinic was about to start a new breast cancer center. Finally, when asked what was the most educational activity for them, eight out of the 16 who answered this question indicated the IGDG, five indicated the discussion they had with the medical provider, and three noted the mammography brochure.

Another tool that we used during the formative research was the PDSA cycle.^{36,37} The PDSA cycle was primarily used to test two activities; the physician recommendation letter, and the IGDG. Regarding testing the physician recommendation letter we found out that the preparation and mailing out of the letters took place as planned and no further modifications were needed. Regarding testing the implementation of the IGDG certain modifications took place such as reducing the time of answering each self-reflection question to three minutes, and a short break was added to the agenda after the self-reflection portion was completed.

A summary of the results of the process evaluation can be found in Table 2.

Qualitative research

The qualitative portion of the evaluation consisted of two focus groups (N=4 participants in total) with research participants who completed both the pre and post-surveys and one key informant interview with the medical director of the clinic. The results of the qualitative research cover both process and impact evaluation.

The demographic characteristics are presented below. Two of the participants were 50–59 years old, one 60–65 and one older than 65 years old. In regards to education, two participants indicated completing some college work, one completed an associates' degree and one some high school education. Half of them lived in town and half in a rural community. Two participants were divorced, one married and one widowed. In regards to employment status, two were fully employed, one was part-time employed and one unemployed. Moreover, half of the participants had an annual gross general income of up to \$19,000, one less than \$10,000 and one over \$50,000. Three of them stated they already received a screening mammogram and the fourth one that she scheduled one (which was later confirmed as “received”).

All participants were familiar with the program, its components and its purpose. When asked what was particularly useful about the program, an emergent theme was the IGDGs. A few participants noted that the program needed more exposure to the community and that some women needed to participate in more than one IGDG so that they could start “opening-up” and sharing information with others. Overall, all participants were satisfied with the implementation of each intervention activity. Some indicative comments were “detailed, very well put together” in reference to the mammography brochure and “I am so proud to have it (the bracelet) and wear it. It’s an easy way to begin a conversation around cancer and prevention.” Interestingly enough, women voiced mixed opinions regarding their experiences with the medical providers. Some women expressed great satisfaction with their medical provider (talked about mammogram, went over the brochure), however, one indicated that her provider was not knowledgeable about the project and had to be reminded by her about it. Also some women said that some medical providers did not give out the brochure.

In terms of impact, an emerging theme was that the participants through the NWHP became more vocal about breast cancer and that more friends and family members came to them for questions about mammography. Another idea that arose was that some women because of the program became more conscious about their own health. As one participant said

“education is power.” Finally, in terms of recommendations for future implementations, women suggested a broader exposure of the NWHP in the community, and scheduling more frequent IGDGs.

In addition to the focus groups, we also conducted an interview with the medical director. The medical director said that all parts of the intervention took place (patient-doctor guided communication, recommendation letter and delivery of the brochure), except for discussing the brochure with the patient. Regarding the question “What was the most useful tool of the clinic-based component?”, he indicated the decision-stage form because it gave him an idea of the educational gaps women had. As he said “sometimes if you don’t ask, you don’t know what the women think about.” When asked about the mixed reactions the research participants had in regards to discussing mammography screening with their medical providers, his response was that despite all the information that was disseminated to his colleagues, they thought that the counseling part was too complex.

The medical provider rated the project in a scale of 1–5 (5 being excellent) with a “4” because it provided the basics of screening and it was culturally appropriate. On the other hand, according to him, the NWHP did not last long enough to give him and his colleagues enough time to “process the tools we created.” Finally, in response to our question how we could promote the clinic’s staff involvement in the study, for instance through the provision of incentives, his response was that providing incentives was unnecessary if the administration truly supported the project. In our case, according to him, the new leadership of the clinic, viewed the project as external to the clinic’s operation, and that it inherited the project from the previous administration. There was no zeal for the project and the new administration never “bought into it (the project).”

Results based on the Evaluation Survey

Twenty-nine women participated in the study, of which 21 were retained (72% retention rate) until the end of the study and completed the post survey. The primary purpose of the quantitative analysis was to determine if the intervention has shown promising positive effects toward the goal of increasing mammography screening, and to identify factors that are predictive of getting a mammogram.

By the end of the project in December 2014, seven (33%) out of the 21 participants indicated that they got a mammogram in the post-survey (within 3–5 months following the study entry) and four received a mammogram within 6–12 months following the entry to the study.

Therefore, as of total, 11 (52%) women underwent mammography screening within one year of entering the study.

The descriptive baseline data analysis results showed that none of the women had a mammogram for the last 2 years or more prior to entry to the study. In addition, only one out of five women had an annual Professional Breast Examination, and only 55% intended to get a mammogram within the next 3–5 months. Only 22% identified screening mammography and Professional Breast Examination as the recommended modalities for early detection of

breast cancer and the majority of the women (40%) indicated that 30 years old was the appropriate age to start screening mammograms. More information about the demographic information of the sample can be found in Table 3.

In total, 11 out of 21 (52%, 95% confidence interval [CI]: 30% to 74%) women underwent mammography within the 3–12 month follow-up period post entry to the study or six months follow-up to the end of the intervention. In addition, six out of twenty (30%) women improved their intention to undergo mammography during the course of the intervention (95% CI: 15 % to 52%). Among the 10 participants who did not undergo mammograms and did not have a mammogram scheduled, seven (70 %) indicated that they were likely or very likely to obtain their next mammogram within the next 3–5 months (95% CI: 35% to 93%). In fact, three out of the seven got a mammogram within 22 months' post entry to the study.

Due to the small sample size and skewed distributions, the parameter for comparison between the groups across the theoretical constructs as defined by the Theory of Planned Behavior^{26,27} is the median and not the mean. None of the score difference was significantly different between the women who got the mammogram and the women who didn't (two sided Wilcoxon rank-sum test) (data not shown). Regarding knowledge, there was no significant difference in knowledge among those who got a mammogram and those who did not. By doing additional explorative research (data not shown) there was not much change in the specific categories of response between the pre and post levels regardless of the mammography status. For example, at the pre level, 12 women indicated that the first mammogram should start at the age of 30. Among those, 92% retained their answer at the post level.

DISCUSSION

The study aimed at promoting regular mammography screening and decreasing health disparities by addressing multiple system levels, that is the individual, family/social support, organizational/practice, and finally the community/environmental levels. Research has shown that addressing multiple levels of interventions is the most effective way to decrease health disparities including breast cancer disparities.³⁹

The primary purpose of this evaluation was to assess the feasibility of this culturally-appropriate and theory-based intervention study and its initial impact of a group of AI women who did not have a recent mammogram. We tried to answer two main questions: "Can the intervention work" and "Does it work"? Given some evidence that a treatment might work (feasibility), the "does it work" question refers to whether the intervention can be implemented under ideal (efficacy evaluation) or actual conditions (effectiveness evaluation) compared to other practices.²³

Ideally, feasibility studies take place prior to efficacy studies and produce a set of findings to help determine whether an intervention should be recommended for efficacy testing or not.²³ However, in this study we addressed all three levels at the same time. We were able to demonstrate that the NWHP can work and does have some impact. Part of the impact was

tested in ideal conditions (e.g. the IGDGs) and some in actual conditions (e.g. the patient-doctor guided communication).

The results of the process evaluation reveal a high reach in both components (clinic and community) ranging from 80% (community-based component) to 100% (clinic-based component). In addition, the results of the process evaluation indicate that some of the intervention targets (i.e. IGDG) were implemented as planned; however, some were not fully implemented such as the patient-doctor guided communication and the mailing out of the recommendation letter. This conclusion derives from multiple sources of evidence based on the results of the qualitative and quantitative research. The fact that parts of the intervention were not fully implemented may have lent to a Type III error which states that an intervention might not be proven effective not due to its theoretical design, but due to the fact it was not fully implemented.⁴⁰ On the whole, it was more difficult to implement the clinic-based component (i.e. patient-doctor guided communication, conversation over the breast cancer brochure and mailing of the recommendation letter), rather than the community-based component because the research team did not have much control of the implementation of these activities.

These activities were implemented solely by the clinic staff in a real-world setting which meant that the implementation was prone to external factors that might have occurred during the implementation such as staff turnover. Ideally, we would have liked to test the patient-doctor guided communication through the PDSA cycle, however, we were unable to do that in order to protect the patient's privacy.

Another useful observation derived from process evaluation was the fact there wasn't a strong linkage between the clinic and the community-based components. In other words, some women after they had completed their visit with the physician were reluctant to participate in the IGDG. Based on successful interventions on tobacco control, approaches for linking clinical and community services include such things as computer-linked systems where referrals are automatically made from a clinician to a community-based program and vice versa, or a fax referral system that links providers with community-based quitlines and vice versa.⁴¹ One possible way in future replications of our study to link the community and clinical components is to create a referral from the medical practitioner's office to attend the IGDG. Integration of effective clinical and community-based strategies across the multiple levels of the socio-ecologic framework expands the availability of services at the levels of influence that may be most accessible to different individuals, thus making utilization of available services more likely.⁴¹

In terms of behavioral outcomes, at least half of the research participants got future mammograms, a finding that indicates a moderate success of the study. Similarly, intention to get a future mammogram was increased which further provides evidence of the success of the study. This finding is particularly important considering the fact that none of the research participants had a mammogram within two years prior to their entry to the study. The results of this study are similar to the results of the only similar study by English.¹¹ During this study all 39 women who participated in the study got a future mammogram, however, the participation in mammography screening was promoted by the research team in an

organized way through designated “Mammography Days” and through the provision of transportation. In our study, the uptake of future mammogram was left entirely to each individual woman which made the task more challenging but yet more realistic.

Qualitative research revealed that the research participants through the IGDGs became more conscious about breast cancer and ready to undertake preventative action. In fact, some women became “resources” themselves, and were eager to talk about breast cancer to other women and encourage them through their own example of having a mammogram to also have a mammogram. Using the Freire^{33,34} approach of raising consciousness was an innovative way to spark the women’s interest and enthusiasm on breast cancer prevention and early detection.

Interestingly enough, there was no enhancement of knowledge on mammography screening among the research participants. However, this is not discouraging nor surprising because the main public health message we were trying to convey was for women to consult with their primary medical provider and get regular screening mammograms according to his/her recommendation. In addition, it was evident from the evaluation surveys we completed at the end of each IGDG and during the focus group discussions that women became more knowledgeable on other aspects of breast health. For example, they became more knowledgeable on the importance of being aware of breast related changes, and that breast cancer affects all women and not only the Caucasians.

From a system’s perspective, the study promoted sustainable changes at the clinic with a potentially long-term impact. Specifically, the bulletin board poster and the mammography screening flowcharts are still being used at the clinic upon completion of the project. Moreover, we developed educational tools such as the decision-stage forms, and the breast cancer brochure that were left with the clinic personnel for their use as needed. The study also introduced new practices at the clinic in relation to patient counseling on mammography screening.

Our study also highlights the importance of context and context evaluation.⁴² The NWHP was launched at the time when there was clinic leadership turnover. This resulted in delays in staff recruitment, project implementation and ultimately to a partially engaged partnership between the university partner and the clinic administration. Nevertheless, the partnership survived primarily due to the continuous support from the tribal leadership, and the existence of the tribal resolution. Overall, the administration helped us in multiple ways such as providing us with resources (e.g. office space), access to the clinic’s medical records, and most importantly through its participation in the CSC.

Another example of the importance of context evaluation refers to the launching of a mammography center at the tribal clinic toward the end of the study. We hypothesized that the presence of the center might influence the uptake of screening mammography. A related question was included in the post-evaluation survey to assess that possibility. Only two women indicated that they have decided to get a mammogram after they had found out that a mammography center would be launched at the clinic which might indicate that the center’s effect was not as big as we thought it would be.

From a methodological perspective the use of CBPR was instrumental in conducting this evaluation. Having community members conduct research (survey administration, participant recruitment, and qualitative research) requires training, supervision and patience on behalf of the investigators. On the other hand, CBPR is the only venue to conduct this kind of research especially within AI/AN populations. For example, community members can lend their wisdom as to how to best recruit participants through existing linkages in the community. Community members can also lend their expertise in doing research. For instance, one CRA was a stenographer and thus became the focus group note-taker. This method of matching raw community skills with desired research skills is in line with the concept of building communities from the inside out or the asset approach.⁴³ Through this study we were able to demystify in the community the word “research” and thus build to some extent local research capacity.

From a theoretical perspective, the Theory of Planned Behavior^{26,27} is a useful tool for identifying the motivators and barriers regarding getting regular mammograms. However, it is premature to state that building interventions based on its theoretical concepts will lead to increase intention and future behaviors. Further replication of this study is needed with a bigger sample size and most importantly, allocation of longer implementation time so that the intervention would become more robust or mature as its components would be fully integrated within the clinic and community settings.

The study suffered a few limitations. The first limitation refers to the lack of a comparison group. Such a design would have allowed us to assess whether the observed outcomes were due to secular changes or the intervention itself. Despite our intense efforts, we were unable to secure a similar tribal community that would serve as the comparison group.

A second limitation refers to the small sample size and the moderate response rate which further lead to lack of generalizability. In other words, the results of this study only pertain to this specific AI community in Oklahoma. Replications of the study with different AI/AN communities, in different geographical regions and with bigger sample sizes can enhance generalizability of the results.

Difficulties in recruiting AI/AN research participants are not uncommon.⁴⁴ In fact, a similar study also utilized a small number of research participants.¹¹ Recruitment was limited by the fact that only active patients at the clinic were allowed to enter the study. In addition, the potential participants needed to have already scheduled an appointment with a medical provider at the clinic within a month. These restrictions minimized our pool of potential research participants. We were faced with the dilemma of either having a small number of research participants or not having participants at all (in the event we did not abide by the clinic’s guidelines). We opted to the first option which allowed us to be able to conduct the study, albeit with a small number of research participants.

In addition, we experienced difficulties in contacting the potential research participants which was done primarily via phone. The use of lay health advisors could have enhanced the recruitment process but this option was not feasible at the time of the study implementation.

In future replications of similar studies, we strongly recommend that more emphasis and resources are being allocated in participant recruitment.

TRANSLATION TO HEALTH EDUCATION PRACTICE

The study has several implications for health educators. From a programmatic perspective, multi-component interventions, provided they are well implemented can promote sustainability. Health educators need to be thinking about sustainability as early as in the planning phase and always strive with their community members for programs that do not only focus on short-term impact (e.g. increase in knowledge) but mostly on long-term impact (e.g. policy changes). On the other hand, multi-component interventions are complex and require lots of resources. Ample time is needed for the intervention's full implementation so that it becomes mature, and fully integrated within the settings or entities is taking place.

A second implication is the importance of active participation of the community members who will be ultimately benefiting from the program. Active participation of the community throughout the stages of program development and evaluation is vital to ensure that the programs we create are culturally appropriate, well supported by the community members and ultimately feasible. Health educators need to create supporting structures such as community-based advisory boards or even better local community research teams who will assist them in the implementation and evaluation of a program.

Another implication of the study relates to the evaluation of health promotion programs especially at community settings. Evaluation can be a "messy" undertaking as the researchers are constantly trying to balance scientific rigor with practicality. This is not surprising since communities are diverse, dynamic, and complex. Therefore, it is important that evaluation is rigorous while at the same time easy to implement, and helpful for the communities we work with. Health educators can work closely with the community members to design the appropriate evaluation tools, and methodologies to collect the required data. Emphasis should also be put in process evaluation by incorporating a planning model such as the one by Steckler and Linnan.³⁵

A final implication relates to the importance of qualitative research especially in the evaluation of community-based programs. Quantitative research does not always produce statistically significant results that will allow us to decipher if the program is effective or not. Qualitative research can be used complementary to quantitative research to enhance its results or shed light to areas that the quantitative research cannot capture. Evaluation of health promotion programs is like a "puzzle picture" and to complete the puzzle all pieces need to be present. The use of both qualitative and quantitative research can provide most of the pieces of the evaluation puzzle picture and help us understand as to why the intervention worked or did not work.

To conclude, theory-based interventions promoting breast health among AI communities by using multiple level intervention targets at the clinic and community settings via CBPR are feasible and efficacious. More research is needed to test the implementation of similar

interventions with an ecological focus among different AI/AN populations and by utilizing more complex evaluation designs.

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Fig. 1. Theory of Change based on an expanded model of the Theory of Planned Behavior (TPB)
 The squares refer to the TPB, the circles to the secondary constructs, the 3-D diagrams to the constructs addressed in the intervention, the diamonds to the clinic-based activities and the hexagons to the community-based activities.

Table 1.

Process evaluation component matrix

Component & Definition	What will be evaluated/Related research questions	How will be measured
Context (Aspects of the larger social, political, and economic environment that may have influenced intervention implementation.)	Barriers influencing the delivery of the components of the program: A) Patient-doctor guided communication; B) Educational brochure; C) Mailing out recommendation letter by physician; D) Constraints attending intergenerational discussion group.	A) Physician Log; B) Interview with physicians at the end of the program; C) Tracking logs by project staff; D) Follow-up phone calls with participants who missed the intergenerational discussion group.
Reach (Proportion of intended target audience that participated in an intervention.)	A) Percent of research participants who had a patient-doctor guided communication; B) Percent of women participating in the discussion group.	A) Copies of the decision making forms returned; B) Sign-up sheet, comparison of those women who were supposed to come vs. those who actually showed up.
Dose delivered (Number or amount of intended units of each intervention or each component delivered or provided.)	A) Extent to which physicians have guided communication with patients, length of discussion; B) Did the medical providers find the guided communication meaningful/beneficial? C) Number of brochures distributed by physicians; D) Number of brochures given out to clinic, sent to patients by mail or in person via discussion groups; E) Number of physician recommendation letters mailed out; F) Extent to which all components of the inter-generational discussion groups took place.	A) Physician Log; B) Interview with physicians; C) Keep track of brochures delivered, physician log; D) Post evaluation survey, focus groups with research participants; E) Tracking by project coordinator; F) Facilitator check off list for discussion groups.
Dose received (Extent to which participants actively engaged with, interacted with, were receptive to, and/or used materials or recommended resources.)	A) To what extent the participants actually had a guided communication with the physician? B) Number of participants receiving the brochure; C) Number of participants receiving the recommendation letter; D) To what extent the participants benefited from the overall program?	A) Post survey evaluation, Focus group discussions with research participants, Physician Log; B) Post evaluation survey; C) Post evaluation survey; D) Focus groups with participants.
Fidelity (Extent to which the intervention was delivered as planned.)	Did all the intervention components take place as planned?	Physician log, Discussion with physician, Focus groups with participants, Post evaluation survey, Facilitator check off list, Review of the Logic Model.

Process evaluation results

Table 2.

Component & Definition	What will be evaluated/Related research questions	Results
Context (Aspects of the larger social, political, and economic environment that may have influenced intervention implementation.)	Barriers influencing the delivery of the components of the program: A) Patient-doctor guided communication; B) Educational brochure; C) Mailing out recommendation letter by physician; D) Constraints attending intergenerational discussion group.	<ul style="list-style-type: none"> Program needed more community exposure and visibility; Women should be invited to more than one intergenerational discussion groups; Physicians needed more time to process the educational tools created; Project material was not always in the examining room; Some medical providers thought counseling was too complex; Clinic director too overwhelmed with existing clinic tasks to dedicate ample time and resources to this program; Not "buying in" from clinic leadership.
Reach (Proportion of intended target audience that participated in an intervention.)	A) Percent of research participants who had a guided communication with physician; B) Percent of women participating in the discussion group.	<ul style="list-style-type: none"> 29 eligible research participants- only 21(72%) of them returned the post survey and participated in the program; All of them (100%) met with the medical provider; Approximately 80% participated in the discussion groups.
Dose delivered (Number or amount of intended units of each intervention or each component delivered or provided.)	A) Extent to which physicians has a guided communication with patients, length of discussion; B) Did the medical providers find the guided communication meaningful/beneficial? C) Number of brochures distributed by physicians; D) Number of brochures given out to clinic, sent to patients by mail or in person via discussion groups; E) Number of physician recommendation letters mailed out; F) Extent to which all components of the inter-generational discussion groups took place.	<ul style="list-style-type: none"> 9 completed physician logs on guided communication with patient returned to evaluation team; 14 copies of decision-making stage forms were returned to evaluation team; All intergenerational discussion groups took as planned; All components of the intergenerational group discussions took place with the exception of the breast cancer survivor presentation (2/6 sessions).
Dose received (Extent to which participants actively engaged with, interacted with, were receptive to, and/or used materials or recommended resources.)	A) To what extent the participants actually had a guided communication with the physician? B) Number of participants receiving the brochure; C) Number of participants receiving the recommendation letter; D) To what extent the participants benefited from the overall program?	<ul style="list-style-type: none"> 12 (63%) participants indicated that physician actually talked to them about mammography; 13 (61%) participants indicated that they had the opportunity to ask the medical provider questions during their visit; 12 (60%) participants said that they did not receive the physician's recommendation letter; 18 (85%) participants received breast cancer brochure-among those seven still remembered the importance of mammography as highlighted in the brochure; Participants enjoyed discussion groups- learned about importance of regular mammograms, knowing one's body, that breast cancer runs across ages and race/ethnicity, and the importance of sharing information with family and friends; Most educational component- Intergenerational group discussions; Satisfied with most components of program, mixed feelings about the patient-doctor guided communication; All women who got a screening mammogram within the time of the intervention received the bracelet.
Fidelity (Extent to which the intervention was delivered as planned.)	Did all the intervention components take place as planned?	<ul style="list-style-type: none"> Most of the activities of the clinic-based component took place as planned with the exception of the physician's recommendation letter; Most of the community components (i.e. inter-generational group discussion) took place as planned.

Table 3:

Descriptive survey results at baseline (N=29)

Variable	Levels	N	Percent
Age	Mean 59 years (Min 52, Max 71, STD 5.56)	29	
Marital status	Divorced	14	48%
Employment status	<ul style="list-style-type: none"> Disabled and do not work; Unemployed or Homemaker; Full time employed; 	8 6 8	29% 22% 29%
Education	<ul style="list-style-type: none"> Some college/junior college, but did not graduate from four-year college; Graduate from High school or completed GED. 	13 8	48% 29%
Income	Under \$45,000	25	86%
Rural area	Yes	6	21%
Private health insurance	<ul style="list-style-type: none"> Yes 	16	55%
Treated for breast cancer	<ul style="list-style-type: none"> Yes 	0	0%
Family history-mother	<ul style="list-style-type: none"> Yes 	8	28%
Ever heard of screening mammograms	<ul style="list-style-type: none"> Yes 	27	93%
Ever mammograms	<ul style="list-style-type: none"> Yes 	27	93%
When was the last mammogram	<ul style="list-style-type: none"> 2 years ago; 3–5 years; More than 5 years. 	15 9 4	54% 32% 14%
Where was the last mammogram	<ul style="list-style-type: none"> Hospital; Mobile clinic; Public Health Center. 	17 4 2	60% 14% 7%
Time travel required to mammogram location	<ul style="list-style-type: none"> Between 31 minutes and one hour; Over an hour; Between 16 and 30 minutes; Less than 15 minutes. 	14 4 4 2	50% 14% 14% 7%
Professional breast exam	<ul style="list-style-type: none"> Every year; Every 2 years; Every 3–5 years; Only once; Never. 	5 5 9 4 5	18% 18% 32% 14% 17%
Primary healthcare provider	<ul style="list-style-type: none"> Yes 	26	90%
Intent to have a mammogram within next 3–5 month	Likely/Very Likely	15	55%
Knowledge of age at first mammogram	<ul style="list-style-type: none"> 30 years' old 40 years' old 	18 9	67% 33%
How often screening mammogram	<ul style="list-style-type: none"> Every year; Every 2 years; Every 3 years; Never 	11 9 5 2	41% 33% 18% 7%
Early detection of breast cancer	<ul style="list-style-type: none"> Screening mammography and Professional Breast examination only; Screening mammography, Professional Breast examination and Breast selfexam; Professional Breast exam and Breast self-exam only; Breast self- exam only; Screening Mammography only. 	6 11 4 3 3	22% 41% 15% 11% 11%