Award Number: DAMD17-99-1-9310

TITLE: National Native American Breast Cancer Survivor’s Network

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those of the author(s) and should not be construed as an official
Department of the Army position, policy or decision unless so
designated by other documentation.
The Native American Breast Cancer Survivors' Support Network (DAMD17-99-1-9310) is a three year-project supported by the Department of Defense. This project is being conducted by Native American Cancer Research in collaboration and partnership with the National Indian Health Board. The purpose of this project is to improve the survival from breast cancer and quality of life after being diagnosed with breast cancer for both the patient and loved ones of the cancer patient. The study objectives follow: (a) using key and well recognized Native American cancer leaders from geographically diverse regions of the country, identify and recruit Native American breast cancer patients into the survivors’ network and database; and (b) refine, and evaluate the survivor’s database to determine patterns of disease and patterns of care experienced by Native American breast cancer survivors. The intended population is Native American breast cancer patients, both genders, ages 20 and older, living anywhere on the North American continent.

Preliminary findings include documentation that Native breast cancer survivors are not receiving quality care, less than one-third have access to insurance (and thus access to improved quality of care) and standard protocols used with other survivors are ineffective with Native cancer survivors.

14. SUBJECT TERMS:
breast cancer, survivors, American Indians, Alaska Natives

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Introduction

The Native American Breast Cancer Survivors’ Support Network (DAMD17-99-1-9310) is a three year-project supported by the Department of Defense from March 2000 through February 28, 2003 (grant period approved by DoD April 10, 2001). This project is being conducted by Native American Cancer Research in collaboration and partnership with the National Indian Health Board, the Native CIRCLE, and the Center for Healthy Aging. The project addresses various support issues for those dealing with breast cancer and to learn more about how cancer is affecting Native communities. The purpose of this project is to improve the survival from breast cancer and quality of life after being diagnosed with breast cancer for both the patient and loved ones of the cancer patient. The study objectives follow: (a) Using key and well recognized Native American cancer leaders from geographically diverse regions of the country, identify and recruit Native American breast cancer patients into the survivors’ network and database; and (b) Refine, and evaluate the survivor’s database to determine patterns of disease and patterns of care experienced by Native American breast cancer survivors. The intended population is Native American breast cancer patients, both genders, ages 20 and older, living anywhere on the North American continent.

The University of Colorado Multiple Institutional Review Board (COMIRB) approved our application on March 14, 2001 (i.e., annual approval).

Preliminary findings include information collected from concurrent support by the Susan G. Komen Breast Cancer Foundation and California Community Foundation. Findings are not limited to the following:

- Less than one-third of the Native survivors have health insurance.
- Contrary to anticipated findings, we are not seeing a significant difference in quality of cancer care for urban dwelling American Indians as compared to reservation-based Natives.
- A factor which is directly affecting quality of care is access to private insurance versus use of Indian Health Service (IHS) Contracted Health Services (CHS).
- As was identified last year, we continue to find patients from the latter group do not have access to a second opinion for their diagnosis.
- We have identified four women who had lumpectomy without radiation, clearly inadequate care.
- In addition to the cancer facility which was described last year as providing inadequate care for Native patients, a second major cancer care facility for Native American breast cancer patients has statistically significant medical record inaccuracies, rendering their medical records to be of no valid measure.
- The interval between biopsy and initiation of cancer care remains an average of six months. The longest interval thus far is ten years.
- Three Native men diagnosed with breast cancer have contacted the Network and requested support, one of the men have been enrolled in the Network.
- The witness listening in during implementation of the informed consent process is unacceptable by both the interviewer and the patients.
- Ms. Gilbert, Director of the Network, and the P.I. are in the process of training two women to be dedicated to interview data collection rather than relying on Advocates or referring personnel to administer surveys.

Body

Beginning August 2001, we are encouraging community members to assist with referrals of cancer patients to the Network. During the last six months, the majority of referrals have been from community members rather than from leaders in American Indian and Alaska Native organizations. The Native CIRCLE and Native WEB remain among the more active referral sites. Phoenix Indian Medical Center has also begun to actively refer patients. The Internet has also been another good source from people finding our Web Page and contacting us. The National Susan G. Komen Breast Cancer Foundation has a Hot Line that also refers
women to our program. The Director, P.I., and California site coordinator (Restivo) do many public speaking engagements throughout American Indian and Alaska Native communities and referrals are also generated from these presentations.

Key Research Accomplishments:
A 18-month Report (March 2000 through September 2001)
Approved Statement of Work

Reminder: Due to UCHSC COMIRB shut-down, the project did not begin until March 2000. Thus, this September 20, 2001 Report is actually our 18 month report.

Task 1: Refine the plan for active recruitment into the survivors’ database for all participants of the Social Network, Months 1-3

a. Review pilot data from on-going Komen/Breast Ca Fund survivors’ network project
b. Modify intake instrument based on Advisory Board’s recommendation
c. Modify survivor’s computer intake and follow-up database program to be consistent with revised intake instrument
d. Co-investigators train data manager
e. Modify consent form based on Advisory Boards recommendation
f. Submit application to COMIRB
g. Train site coordinators on confidentiality and intake data protocols.

Progress to Date: All of the above have been accomplished. We have continued to refine the recruitment plan and now encourage volunteer referrals from community members. This is proving to be a better source of recruitment than were key leaders and Native organizations or Cancer Centers.

Project staff have recommended that minor modifications be made to the intake instrument to improve the flow during administration. These have not yet been made since the Network Director and P.I. are in the process of training two individuals to conduct all intakes and the modifications may be unnecessary.

Annual IRB approval was received 03/15/01 from the University of Colorado Health Sciences Center.

Task 2. Collection of Survivors’ Intake data, Months 4-33

a. after receiving the breast cancer survivor referral, the site coordinators and PI contact the patient and collect informed consent and intake data. 30-minute phone cards will be mailed to those Native Americans who do not have phones. Estimate 100 survivors in Year 1, 200 in Years 2 and 3.

We continue to have difficulties collecting the “witness” during informed consent for the same reasons as specified in September 2000 report:

(1) To maintain privacy:  
a. The patient usually prefers to be alone for the telephone interview  
b. Other family members and friends may not know of the diagnosis (thus this process of having a witness on line violates both privacy and confidentiality)  

(2) The DoD mandate implies access to more than one phone. However, in many of the households (of both the patient and the interviewer), there is only one phone in the household.
In addition some of the patients use a pay phone to call us and thus there is no witness accessible;

(3) The interviewer must make the call from a confidential setting, which is typically from her home when she is alone—thus no witness is available

(4) The DoD mandate for having this witness on the phone while the informed consent is being delivered is perceived as the DoD distrusts the honesty and ethics of our staff. In addition, patients have asked the staff what we did to deserve such an invasive mandate (e.g., raises distrust of the staff by the patients)

The DoD response received winter 2001 to these issues was that we did not provide a suggestion for how to handle this barrier. Indeed we had. In our September 2000 report (and we continue to make the same suggestion) we requested that this DoD mandate for a witness be removed. Rather than protecting human subject's rights, it actually violates both the privacy and confidentiality of the Native patient.

We feel we can successfully implement the informed consent process and protect the human rights of privacy of our participants. This witness is an intrusion to the confidential nature of the informed consent process and is proving to be a barrier to recruitment to the study and subsequently to attaining our project goals.

For example, if we were able to include the Network breast cancer patients who are within the Komen arm of the study, we have approximately 200 participants. Since we are in month 18 of this project, that 200 participants would put us on schedule for attaining sufficient recruitment into the cohort (i.e., by the end of year 01 we were to have 100 participants and by March 2002, we should have 300).

Last year we had reported difficulty during the first six months of the project obtaining phone cards. However, that problem has been resolved and the women are receiving phone cards with their project information packets.

**b. Intake forms are submitted to Rick Clark of Morning Dew Productions for data loading and correction. Estimate 100 intakes in Year 1, 200 in years 2 and 3.**

Intakes have been loaded by Mr. Clark of Morning Dew Productions and Ms. Tvhokne Harjo, NACR student assistant, into the Survivors Database. We currently have 240 Native cancer survivors enrolled in the Network, but less than 100 have interviews primarily due to the DoD-imposed barrier during the informed consent process.

**c. Dr. Dignan verifies accuracy of data entry by randomly selecting 10% sample of intake forms and performing an independent data load. Inconsistencies will be discussed and re-training will occur. If deemed necessary.**

Dr. Burhanstipanov has verified data quality for the initial 50 intakes loaded into the program. We discovered some minor computer programming errors which have been corrected. Dr. Dignan will conduct data quality control analysis using a randomly selected 10% sample of intakes.

**d. Link Native Americans to related on-going projects – Native American breast cancer support resources and services (i.e., link with a telephone support Sister, the six culturally relevant support booklets, videos, pre-paid long-distance phone cards).**
All support materials mailed to Native patient participants and referral to additional support has continued. This aspect of the project is much greater than was originally anticipated. Almost all of the survivors need additional assistance. Most are not receiving quality care (e.g., lumpectomy without radiation). Several have transportation challenges to obtain care. Many have child care issues (e.g., the patient is a single parent or the partner works away from home for several weeks at a time). The co-morbidity is high among this population. Diabetes, arthritis, high blood pressure and drug-dependence are common conditions. The director of the Network has used local, regional and national resources to help the women find assistance for these additional problems.

Task 3. Collection of medical records and verification of self-reported data, Months 4-33.

a. Review and modify, if necessary, the medical record abstract protocols used for Alaska Native Tumor Registry

As reported in Year 2000, The Alaska Native Tumor Registry medical record abstraction protocols were reviewed by the P.I. and found to be insufficient and included recommendations that initially led to excessive errors. The greatest difficulty was the inability to track from the time of diagnosis to treatment and side effects of treatment / disease. No further information in 2001.

b. For those survivors who agreed to have copies of medical records sent to the Survivors’ Network, the site coordinators will request copies of medical records. A $15 fee will be sent to the medical provider’s office to cover photocopying expenses and staff time to copy files. Estimate 75 survivors in year 1(e.g., delay of receipt), 175+ in Year 2, and 225+ in year 3.

The medical records protocols continue to be refined, particularly in response to recent passage of legislation and status of medical records’ privacy. Significant treatment issues and medical record errors have been identified in two geographically diverse health care settings. In addition, Native breast cancer patients from one geographic region have not received quality cancer care; no established treatment protocols were followed; no follow-up recommendations were sent back to the patients’ home village, no annual check-ups were documented with medical health care records. One clinic within this service area had treatment information on 3 X 5” index cards stored in the bottom drawer of an employee’s desk.

For a second major health care facility that uses CHS for cancer services, a review of medical records by on site oncology nursing staff has documented errors in the medical record related to the diagnosis, staging, treatment protocols. The most significant errors have been insufficient documentation of the cancer diagnosis and care provided to the patient. For example, (a) the cancer stage at diagnosis is missing from the records; (b) the cancer treatment recommended in the medical records differs in reality from the treatment received by the patient (e.g., standard care medications are not available from this facility resulting in the patient receiving lower quality medications); (c) medical oncologist oral history to be transferred to the medical record is incoherent and unable to be transcribed into the record; and (d) the medical oncologist fails to specify a standard protocol to be followed which results in inconsistent, haphazard treatment being given.

These issues were raised with administrators in both settings. In one, the oncologist retired and was replaced by a well qualified, dedicated oncologist and these medical record errors, as well as non-compliance with NCI PDQ treatment protocols are believed to have been addressed. However, records prior to his hiring in October 2000 are still in error.
In the second setting, the oncology nurse has been attempting to work with the oncologist to improve his documentation for the Native patients. Of interest is that review of this oncologist's documentation for his patients at the cancer center where he works 80% time are meticulous. But his records of Natives at the Indian Center are incomplete, unreadable, and inconsistent in protocols. The local nurse has raised this with Hospital Administration but they fear losing him as a contracted health service (CHS) provider and have not taken efforts to correct the situation. The oncology nurse has subsequently trained the nursing staff to file duplicate documentation on patient care. Medications that have serious contraindications when taken concurrently were immediately documented and the nurses refused to administer the additional drugs until the physician spoke with her regarding the medication concerns. In each instance, the physician was thankful to the nurses for noticing the problem and revised his prescriptions. The hospital administrator is becoming more involved as multiple cases similar to this have been brought to his attention.

c. **Pull relevant data (e.g. staging, histologic grade, recommendations for treatment, recommended site follow-up care) from medical records and load into survivors database.**

We have found several medical records which have treatment specified, but no staging information was included. This is a significant problem and we continue to struggle to find a way to verify stage at diagnosis and interval from biopsy to initiation of treatment.

**Task 4: Refine database, Months 9-33.**

- Based on preliminary data runs, review data at six months after data collection was initiated to determine database problems while the number of Native Americans in the database is still small enough to be manageable. Month 09.

This was accomplished. We found we had to modify the response fields for several questions by allowing more space for explanations. Few data entry errors were identified. Some of the sequencing of the computer data screens also required refinement. Mr. Clark improves the program within a few days of the problem being identified.

- **Based on the PI and co-investigators’ recommendations, determine which cross tables should be run and when they should be run.**

We have conducted some preliminary frequency runs and among the cross tabulations we will conduct are the following variables:
1. age at diagnosis and stage at the time of diagnosis
2. date of last breast health screening and stage at the time of diagnosis
3. private health care / Medicare insurance compared with IHS CHS cancer care
4. urban and reservation-based
5. health care coverage (variables #3) and stage at diagnosis
6. health care coverage (variables #3) and interval from biopsy to initiation of cancer care
7. stage at the time of diagnosis and standard of care received (NCI PDQ)

c. **Product data run every six months to review accuracy of data and preliminary indications of trends that should be closely documented.**

We began frequency data runs in April and July 2001. Preliminary trends are age at the time of diagnosis, access to private health care insurance, intervals between biopsy and initiation of treatment.
Task 5. Evaluation of the Database, Months 24-36

a. PI and co-investigators produce cross tabulations and run preliminary statistical analysis. Advisory Board reviews and makes recommendations for additional statistical calculations.

b. Preliminary data summarized and included in National Indian Health Board quarterly newsletter. Press releases of other data, as well as clarification that it is only preliminary, be disseminated to tribal newspapers and magazines.

c. Preparation and submission of (1) papers for Tribal Communities; Native (lay population and providers) meetings (e.g., Association of American Indian Physicians, National Indian Health Board Annual Consumers' Meeting, Native Wellness and Women Conference, Society for the Advancement of Chicanos and Native Americans in Sciences, American Indian Science and Engineering Society, IHS Annual Research conference); (3) professional meetings for presentations (e.g., American Public Health Association; ASPO, Endocrine Society Annual Meeting); and (4) professional peer-reviewed journals and publications (e.g., Cancer, Epidemiology).

d. Submission of final report to DOD.

We are currently in month 18 of the project. Dr. Dignan and the P.I. will begin to implement plans to carryout the activities listed under Task 5 above over the next six months.

What We Have Learned about ...
The process of implementing the Survivors' Support Network.

There continues to be a long process from referral of a patient to the Network to enrollment. Factors which contribute to this delay appear to be: (1) the survivor's need for immediate assistance (and emotionally, not able to conceive of "giving" anything at that time, including informed consent or survey participation); (2) the co-morbidity of the survivors requires services beyond cancer treatment which contribute to the interval from biopsy to initiation of treatment (e.g., support extends to problems in addition to cancer); (3) living conditions which require assistance from outside family members and neighbors to assist with family care while the patient travels away from home to participate in treatment (e.g., having to organize others to care for children while the mother travels to cancer care facility for several month's duration); (4) obtaining the "witness" on the informed consent is impractical since the calls are made in private confidential settings; (5) the inservice training of the interviewer is extensive and few who are trained are actually competent interviewers; (6) unwillingness to provide copies of medical records; and, (7) distrust of research and subsequent unwillingness to be a participant in a research study.

Due to the low success rate of gaining adequate informed consent and interview data collection processes (i.e., the research plan) from the project advocates, the Director of the Network and P.I. have determined that two part-time trained interviewers will continue in that role, one based in Alaska and one based in the lower 48 states. By adding two part-time trained interviewers to continue in this
role the advocates will be encouraged to continue recruiting survivors and to nurture relations between their local native health programs and clinics to provide the much needed local survivor support.

What We Have Learned about ...
What Is Really Happening to Native Breast Cancer Patients

Factors which contribute to the long intervals from the time of biopsy (diagnosis) and initiation of care appear to be: (1) lack of private insurance; (2) inaccessibility to quality cancer care and subsequent reliance on IHS CHS cancer care, which typically includes a long referral process for cancer patients; (3) insufficient tracking and follow-up within selected cancer care facilities; (4) living conditions which must be addressed before the patient can travel away from home to participate in treatment; and (5) lack of understanding diagnosis.

Those patients who have no private insurance rely on IHS Contracted Health Services (CHS). Interviews with tribal health clinic personnel conducted during the spring and summer of 2000 indicated that IHS CHS frequently have insufficient funds during the latter part of the fiscal year (e.g., July, August, September) and may be responsible for delays in cancer patients being referred to follow-up care. Thus during those times of the year, the limited CHS monies are reserved for life-and-death emergency services, and referral for diagnostic tests or cancer treatment may or may not be ranked as a priority by the individual who processes CHS requests. The provider, whether paid by the tribe or by IHS, may have little to no influence over this referral for timely follow-up care. This delay in obtaining access to diagnostic and treatment services is among one of the reasons for the poor survival from cancer experienced by American Indians and Alaska Natives.

For those without health insurance (2/3 of study population), most used tribal or Indian Health Service (IHS) Contracted Health Services (CHS). None of the latter group had access to a second opinion for their diagnosis. Only one of the women who used IHS CHS was offered breast conserving surgery (lumpectomy with radiation) and none were offered tamoxifen. Only one woman had benefit of Sentinel Node surgery. The average interval from the time of diagnosis (i.e., biopsy) to initiation of treatment was three to six months. Interviews with twenty Native American cancer survivors, both genders, of cancer sites other than breast (e.g., lymphoma, prostate, colon) had similar findings for this region of the country.

For those patients with private insurance, regardless of setting, there is a shorter interval between biopsy and initiation of cancer treatment and greater likelihood of obtaining standard care. Only one woman had access to Sentinel node surgery. For those patients with catastrophic insurance (i.e., does not include early detection services), the stage at diagnosis is later than for those who participate in regular screening. Only those patients with medical insurance have been able to choose between lumpectomy with radiation versus mastectomy. All but one IHS CHS patients have had mastectomy. Most women who have insurance have been tested for estrogen receptivity and when appropriate, offered tamoxifen. Almost none of the women who have been treated though IHS CHS have been offered tamoxifen by the health care facility (however, oncology nurses have requested tamoxifen from pharmaceutical company and thus provided tamoxifen to some of the patients in CHS).

Five women enrolled in the Network have died of breast cancer within the past 18 months. At least three received inadequate cancer treatment for their stage of cancer at the time of diagnosis.

None of the patients have been enrolled in clinical trials and only two recalled any discussion of clinical trials by their health care facility staff.

The patterns of cancer will require many more patient's surveys to be collected before a "true" pattern is identified. Based upon preliminary information currently loaded in the computer survivors database, half of the patients are diagnosed with breast cancer prior to age 50 (in comparison, one quarter of white women in
national data are diagnosed prior to age 50, and three-quarters diagnosed after age 50). Thus far, it appears that our women are being diagnosed with cancer at an earlier age in comparison with white women. The interval between date of biopsy and initiation of cancer treatment remains an average of six months.

Reportable Outcomes

One peer reviewed manuscript was published August 2001:
Burhansstipanov L and Hollow W. Native American Cultural Aspects of Nursing Oncology Care. 

A second paper is in press which includes a brief section of findings from the Network:

The Director of the Network and the P.I. will be writing an article specific to findings from the Network as one of a series of papers to be published in a supplemental issue of Cancer from the 1st National Native American Cancer Survivors’ / Thrivers’ Conference (November 8-10, 2001) and the 5th National Native American Cancer Research Conference: “Changing Patterns” (November 11-13, 2001).

Patents and informatics are not appropriate to this study.

Conclusions

Although the process for this Network is quite unique from support programs implemented within other cultures, this project is gradually increasing the size of the cohort and we feel that we will be successful in creating a survivors database and being able to document patterns of cancer care among Native American breast cancer patients. Concerns regarding a number of factors including the consent process appear to have delayed recruitment but progress is being made in building the database anyway. The cohort identified and recruited through this project will serve to develop and implement quality of life interventions designed to improve both the quantity and quality of life of the cancer patient and her/his family.

References


Appendices


Final Reports

Meetings Abstracts

The Native American Breast Cancer Survivors’ Support Network has been presented at the following meetings:

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1999 (Presentations in Chronological Order for which Information about the Network was included or highlighted)

- Presented, “Genetic Education for Native Americans” and “National Native American Breast Cancer Survivors Support Network” to the Network for Cancer Control Research among American Indian and Alaska Native Populations, supported by the NCI. Washington, DC. April 9-10, 1999.
- Presented, Native American cancer survivor: how the community can help. Rincon Reservation, CA May 19, 1999.

2000 (Presentations in Chronological Order for which Information about the Network was included or highlighted)

- Presented, “Cancer,” to the Native Elders Research Center (NERC), Resource Center for Minority Aging Research (RCMAR), University of Colorado Health Sciences Center; Denver, CO. January 9, 2000.
2001 (Presentations in Chronological Order for which Information about the Network was included or highlighted)

- Presented, Training #1 for “Native American Breast Cancer Support in Southern California Indian Communities.” Rincon Reservation, CA, January 8-9, 2001
- Presented, “National Native American Cancer Survivors’ Support Network Findings” The President’s Cancer Panel, March, 2001
- Presented, “National Native American Cancer Survivors’ Support Network: Preliminary Findings.” University of Oklahoma’s Wellness and Women Meeting, San Diego, CA March 5, 2001
- Presented, Training #2 for “Native American Breast Cancer Support in Southern California Indian Communities.” Barona Reservation, CA, March 8, 2001
- Facilitated and presented multiple sessions during 3 day, “CDC Tribal Outreach Training,” (which included preliminary data about Native American breast cancer survivors), Denver, CO, May 2-4, 2001

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<th>Personnel Receiving Partial Pay for the Research Effort</th>
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<tr>
<td>Name</td>
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<tr>
<td>Linda Burhansstipanov, M.S.P.H., Dr.P.H.</td>
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<td>Lisa Castro</td>
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<td>Khari LaMarca, M.P.H.</td>
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Participants and faculty who were financially supported to participate in February 2001 In-service Training

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<tr>
<th>Name</th>
<th>Role on Project</th>
<th>Native American</th>
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<tbody>
<tr>
<td>Alice Bradley</td>
<td>Faculty</td>
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<tr>
<td>Colleen Brown Wolf</td>
<td>Survivor Advocate</td>
<td>Yes</td>
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