

1. Protocol Title.

Trends and Patterns of Cancer Staging among American Indians in the Northern Plains

2. Principal Investigator and other personnel.

Co-Principal Investigator

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3. Funding Sources.

U.S. Department & Health & Human Services (DHHS), Office of Minority Health

4. Study sites. List all centers, clinics, or laboratories where the study is to be conducted.

Northern Plains Tribal Epidemiology Center (NPTEC)
Aberdeen Area Tribal Chairmen's Health Board (AATCHB)
1770 Rand Rd.
Rapid City, SD 57702

University of Nebraska Medical Center
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5. Time Required to Complete. State the month and year of expected start and completion times.

Start date: July 1, 2009
Completion date: July 2011

6. Study Summary.

While there is a well-documented evidence for cancer disparities for Northern Plains American Indians, we know very little about the occurrence of cancer involving late stage or unstaged diagnosis. Stage at diagnosis is one of the most important prognostic factors; it is also important clinical information that is used to determine the treatment. Previous research shows that patients from underserved population groups are more likely to be diagnosed at a later stage, which contributes to higher mortality rates. Also, there is some evidence that these patients are more likely to be unstaged, which often means that the patients not receiving necessary tests to determine stage.

AATCHB proposes a study to conduct an analysis of existing data from state cancer registries in North Dakota, South Dakota, Nebraska, and Iowa to study the occurrence of cancer cases with late and unstaged diagnosis among American Indians. We will examine the trend for cancer staging to determine if there is progress made to detect cancer at earlier stage in more recent years. Also, we will conduct an analysis to determine factors that contribute to late and unstaged diagnosis, so we can propose an intervention to increase the use of screening tests for early detection of cancer. Finally, the results from the proposed study will serve as the baseline data to be used to evaluate the effectiveness of the intervention activities.

The proposed study will be conducted as part of Northern Plains Tribal Cancer Data Improved Initiative (NPTCDI) funded by the United States Department of Health & Human Services. The NPTCDI uses the community-based participatory research approach. The tribal oversight committee provides guidance so that the project activities are conducted in a manner that addresses needs of the tribes AATCHB serves and respect the unique cultural heritages of tribes in the Aberdeen Area. AATCHB partners with University of Nebraska Medical Center, which provides technical assistance for management and analysis of cancer registry data, to implement activities for the proposed study. While the cancer registry data does not contain tribe-specific information and we will only report aggregated results, we are requesting an approval from Aberdeen Area IRB to ensure that the study follows all the required procedures and policies in place.

A. BACKGROUND & NEED

In 2007, Aberdeen Area Tribal Chairmen's Health Board received a fund from Office of Minority Health, U.S. DHHS to implement a 5-year project entitled "Northern Plains Tribal Cancer Data Improvement Initiative." One of the objectives of the project is to conduct analysis of existing cancer data to increase understanding of cancer health status among American Indians in the Northern Plains region.

B. STUDY PROCEDURES

B.1. Overview

B.1.a. Goal

The goal is to increase our understanding of cancer burden among American Indians in the Northern Plains region by conducting an analysis of existing cancer data.

B.1.b. Purpose

The purpose of the study is to examine trends and patterns of late and unstaged diagnoses of cancer among American Indians compared to other races.

B.1.c. Objectives

1. Estimate the frequency and rate of late stage and unstaged diagnosis among American Indians and whites (separately) for 4 most common cancers (prostate, female breast, lung, colorectal) and all cancers combined (the most recently available 10 year data - 1997-2006).
2. Examine the trend of late stage and unstaged diagnosis among American Indians compared to Caucasians
3. Identify predictors of late stage and unstaged diagnosis among American Indians compared to Caucasians

B.2. Methods

B.2.a. Organization and Governance

This project will be administered through NPTEC-AATCHB.

B.2.b. Research subject identification

The proposed study will not involve recruitment of any new subjects. Instead, study subjects' information will be identified from existing records from registries of cancer cases in the Northern Plains states, which include Nebraska, North Dakota, South Dakota and Iowa. The number of subjects whose information will be included in this study will be determined by the information obtained from the cancer registry data.

However, state cancer registries report the number of tumors rather than the number of unduplicated patients. Therefore, until we sort out the duplicated cases we will not know the exact number of subjects in the cancer registry databases. However, according to the American Cancer Society report and state cancer registry reports, we can estimate the number of subjects diagnosed with specific type of cancer each year to be the following:

Table 1. Estimated number of annual and 10-year cancer incidence cases in the Northern Plains states (Nebraska, North Dakota, South Dakota, and Iowa)

	Nebraska		North Dakota		South Dakota		Iowa		Total 4 states
	Annual	10 yr total	Annual	10 yr total	Annual	10 yr total	Annual	10 yr total	10 yr total
Female Breast	1160	11600	410	4100	520	5200	1990	19900	40800
Colon & Rectum	910	9100	350	3500	430	4300	1810	18100	35000
Lung & Bronchus	1240	12400	390	3900	500	5000	2590	25900	47200
Prostate	1260	12600	480	4800	580	5800	1910	19100	42300
Cervix	63	630	18.4	184	16	160	106	1060	2034

Data sources: Cancer Facts and Figures 2008 (American Cancer Society) (<http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf>), Cancer Incidence and Mortality in Nebraska 2005 (<http://www.hhs.state.ne.us/srd/CancerReport2005.pdf>), Cancer in South Dakota 2003 South Dakota Cancer Registry (<http://doh.sd.gov/Statistics/2003SDCR/default.aspx>), North Dakota Cancer Incidence Rates by Cancer Type and Race (2001-2005) (the document obtained in 2008; the website for ND Cancer Registry currently under construction, Iowa Cancer Inquiry System (<http://www.cancer-rates.info/ia/>))

Cervical cancer incident cases are based on Nebraska (2005), North Dakota (2001-2005), South Dakota (2003), and Iowa (2005). North Dakota had 92 cases of cervical cancer 2001-2005.

B.2.c. Information to be collected

The proposed study relies on existing information as its data source. No prospective data will be collected. Additionally, no data will be retained for future research projects following completion of the proposed research.

The study requires all the information provided in the cancer registry data except patient identifiers, such as patient names, to be collected for analysis. However, patient zip code and address information, which are considered to be identifiable protected health information, will be used for geo-coding.

1. The following personal identifiers will be retained:
 - a. Case ID used by State Cancer Registries
 - b. Birth date
 - c. Address
 - d. County
 - e. Zip Code

Note: Nebraska Cancer Registry (by statute) routinely collects subject identifiers. However, these identifiers will NOT be transmitted as part of the data provided to the researchers for analysis, because these are not

required to perform the proposed work.

Before transmitting the data to UNMC, the registry will reassign another set of unique ID for UNMC to use. UNMC needs the unique ID in order to identify duplicate cases. The registry staff person who created the unique ID for this UNMC study is the only person who can link the UNMC unique ID to the state registry unique ID. Therefore, the confidentiality of the study participants will be protected.

The information collected from the cancer registries will retain the identifiers until data analysis is complete. This is because case ID information is needed to exclude duplicate records. Birth date will be used to calculate age at time of diagnosis, which is one of covariates in our analysis. Address is needed to identify the county of residence, which is another covariate.

B.2.d. Data Storage and Confidentiality

Data will be stored and accessed at the State Cancer Registries, which will transfer the data to the University of Nebraska Medical Center - College of Public Health (COPH). The COPH will prepare analytical data sets and transfer the original and analytical data sets to Aberdeen Area Tribal Chairmen's Health Board (AATCHB). Data analyses will be conducted at both COPH and AATCHB.

At the COPH and AATCHB, data will be stored on secured, password-protected computer systems, with limited access only for investigators. No data will be transmitted to parties outside of COPH/AATCHB. No data involving protected health information (e.g. subject identifiers) will be disclosed to any commercial sponsor. Disclosure to parties within COPH/AATCHB for the purpose of research will occur only through the duration of the proposed research and until data analysis is complete.

B.2.e. Data Analysis

This is a retrospective population-based study of patients diagnosed with prostate, female breast, colorectal, and lung cancer. To examine the trend of unstaged and late stage diagnosis, incidence rates will be calculated per 100,000 population and were age adjusted by the direct method using the 2000 U.S. standard population (Klein & Schoenborn, 2001; National Cancer Institute, 2005). Incidence rates, rate ratios and 95% confidence intervals (CIs) will be calculated with version 6.3 of SEER*Stat software (National Cancer Institute, DCCPS, Surveillance Research Program, Cancer Statistics Branch, 2007) To identify factors predicting late versus early staged cases and unstaged versus staged diagnosis and late vs. early stage diagnosis, multivariate logistic regression analyses will be conducted. Odds ratios and 95% Confidence Intervals will be obtained in order to evaluate the associations between patient demographic characteristics, time period, and the staging outcome. We will use SAS software Version 9.0, and considered the level of significance to be at $p < 0.05$.

B.2.e. Data Reporting and Dissemination

Results of the proposed analysis will be reported and reviewed by NPTCDI Advisory Committee and Workgroup. The proposed study will conduct analysis to report aggregated results only. The results will be disseminated to tribal communities and their partners in a variety of methods including written reports, presentations, and fact sheets. Upon approval by Advisory Committee, the study may be reported in scientific journals to inform Native American Indian organizations and non-Native American organizations that work to improve cancer health status of Native Americans.

B.2.g. Financial Compensation to the Subject for Participation

This is an analysis of existing data and does not involve recruitment of subjects nor collection of new data. Thus, the financial compensation does not apply.

C. Personnel

Co-PI: Adeola Jaiyeola, Shinobu Watanabe-Galloway

Project Coordinator: Nicole Flom

Tribal Outreach Coordinator: Tinka Duran

Consultants: Corey Smith, Leah Frerichs

Data Analyst: Kate Hansen, Nicole VanOsdel

IV. Protection of human subjects (consent)

The proposed project will not require written informed consent because we will not recruit subjects.

V. Appendices

CV/biosketch of project personnel attached.