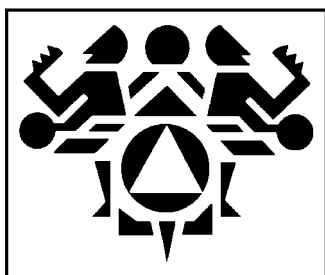


*****Model Research Protocol*****

The Portland Area Indian Health Service (IHS) Institutional Review Board (IRB) would like to thank Francine Romero, PhD, MPH, for granting permission to use this protocol as a model research protocol.

2001 NORTHWEST TRIBAL BRFSS PROJECT
Wednesday, August 14, 2002



Northwest Portland Area Indian Health Board
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Principal Investigator: Francine C. Romero
 Co-investigator: Kathleen McDavid (CDC)
 Technical Assistance: Jay Friedman (CDC), Wyndy Amerson (CDC)

Funding Source

Centers for Disease Control and Prevention, U55/CCU016012-01

Introduction

In an effort to understand the types of health risk behaviors present among the tribal people of Portland Area (Oregon, Idaho, and Washington), the Northwest Portland Area Indian Health Board, through the Northwest Tribal Cancer Control Project, is conducting Behavior Risk Factor Surveillance System (BRFSS)-type surveys in six (6) tribal communities. The tribes have selected the modules and questions to be asked of their tribal members (~300 interviews per tribe, 150 males and 150 females over 18 years of age). Trained individuals from each of the respective local communities will conduct the face-to-face interviews.

Background

Cancer is the second leading cause of death among American Indians and Alaska Natives (AI/AN). Risk factors for developing cancer include age, genetics and environment. Because cancer is a chronic disease with a long latency period it tends to affect older people disproportionately. As life expectancy increases, so too does the proportion of AI/AN at risk for developing cancer. In an effort to augment existing risk factor information on AI/AN and provide population based estimates, we propose to conduct a Behavior Risk Factor Surveillance System (BRFSS)-type survey.

Introduction

In 1984, the Centers for Disease Control and Prevention (CDC) established the Behavioral

Risk Factor Surveillance System (BRFSS) for monitoring health risk behaviors. Since that time, all 50 states have conducted these surveys, as well as many tribes in the Northwest and elsewhere throughout the United States. It is estimated that twenty similar small-scale surveys, with between 300-500 respondents per survey, directed toward AI/AN groups have been carried out in different regions of the United States. The basic philosophy of the BRFSS is to collect data on health-related behaviors that would be useful for planning, initiating, monitoring, and evaluating health promotion and disease prevention programs.

Purpose

In order to increase tribal knowledge of current behaviors among American Indian men and women 18 years of age and older regarding cancer, we intend to conduct BRFSS surveys among members of six randomly selected tribes in the Northwest. The purpose of these surveys will be to assess the knowledge, attitudes, and behaviors of adult Northwest AI/AN males and females with regard to health risk behaviors. This survey will be conducted by the respective participating tribes in collaboration with the Northwest Tribal Cancer Control Project (NPAIHB) located at the Northwest Portland Area Indian Health Board (NPAIHB) in Portland, Oregon.

Methods

We will randomly select six tribes (two each in Idaho, Oregon, and Washington) to participate in these surveys. These tribes will be selected from all tribes in Portland Area with at least 1,000 tribal members. The six surveys will be conducted in relatively large communities instead of conducting fewer surveys in a larger number of communities. Because random samples of tribal members will be drawn, the results will be generalizable to each participating tribe. The results will also allow us to draw general inferences about American Indian adults throughout the three-state area.

We will send a letter to these selected tribes inviting their participation in these surveys. If a tribe declines to participate, we will go to the next randomly selected tribe on the list. A tribe's agreement to participate will comprise formal approval from the tribal health director, health board and tribal council to conduct the survey. The tribal letters of approval will be submitted to the Indian Health Service's and CDC's Institutional Review Board (IRB) upon receipt. In order to ensure a high level of acceptance of the survey and to thereby maximize participation rates, a significant effort will be expended in each participating tribal community to garner support for the survey, to alert the community to the purpose and timing of the survey, and to more generally raise community awareness of the issue of cancer. In order to accomplish this, NPAIHB and each of the participating tribes will hold public meetings and distribute a series of public announcements in the print, radio and television media, as well as through community organizations, to announce the upcoming survey; provide information on its purpose, methods, and timing; and provide a forum for exchange of ideas on the survey and encourage community participation.

The NPAIHB will provide financial support to each participating tribe to support the hire of a tribal project coordinator and tribal interviewers, including their training; local travel by survey staff; the compensation of respondents (\$10 per interview); and, the implementation of strategies that will promote participation in the survey. A local field

coordinator may be hired in each participating tribal community to coordinate the survey activities including the interview schedule and staff. The tribes will have the option to utilize existing staff members as either local field coordinators or interviewers. The local coordinator will be available to answer questions from prospective survey respondents and the general public. The interview staff will be trained in conducting surveys and will be provided printed materials on cancer (e.g., American Cancer Society brochures and other resource materials) that can be distributed within the community. Dr. Howie Goldberg, Jay Friedman and Wyndy Amerson of the Centers for Disease Control and Prevention (CDC)/Division of Reproductive Health (DRH), have agreed to assist with interviewer training, data entry training, and data analyses through a cooperative agreement with the Indian Health Service at no cost to either the tribes or NPAIHB. Mr. Friedman has been an integral part of questionnaire and methodology development. Both Dr. Goldberg and Mr. Friedman have a strong record of successfully completing surveys in tribal communities, including those in Portland Area.

Within each tribe, we will select a simple random sample of up to 500 tribal community members 18 years of age and older from tribal enrollment lists and/or Indian Health Service or tribal health user population lists. The lists would contain a subset of the tribal population 18 years of age or older including the name, date of birth, address and telephone number. The lists will provide us with the most current and comprehensive tribal membership information, thereby enhancing the representativeness of the sample selected for the surveys. The survey seeks to complete between 300 to 400 interviews per community, to do this a random selection of 500 names will be used to take into account refusals, those who have moved, those who died, those temporarily away from the reservation, and loss to follow-up. The resulting sample size (up to 400 respondents in each tribe) will enable us to estimate parameters for the entire tribal community.

Each of the potential respondents will be contacted by the interviewers and invited to participate in the survey. Each respondent will sign an informed consent form prior to the interview. Appendix A contains a copy of the informed consent form. Each interview will require about thirty minutes to administer. Respondents will be compensated \$10 each for a completed interview in regard to their time and contribution. All interviews will be conducted face to face.

After the approval from the tribes and the appropriate IRBs, we will pretest the questionnaire to assure comprehension and flow and to identify any problems. Once these problems have been addressed, the questionnaire will be revised and finalized before implementation.

The questionnaire used in the conduct of these surveys has been constructed for the most part using standard, field-tested modules in common use in the BRFSS system and in small scale surveys among American Indian populations. Topics covered include general demographic and health status questions; disease-specific issues (e.g., diabetes, hypertension, cardiovascular, etc.); use of preventive and curative health care services; risk behaviors (e.g., tobacco use, alcohol use); and, risk-reduction activities (e.g., weight

control, proper nutrition, etc.). Appendix B contains a copy of the questionnaire that will be used in these surveys.

The collected data will be entered at each tribal site. The final data set will be cleaned and edited by CDC/DRH then delivered to the NPAIHB staff for final editing, recoding, and statistical analysis. We will use basic descriptive statistics (e.g., frequency distributions, means, etc.), bivariate statistics (e.g., contingency table analyses, t-tests of means, etc.), and multivariate modeling (e.g., logistic regression, ANOVA, etc.) to analyze the data, as appropriate. Each participating tribe will receive a copy of the final dataset. The software (SURVEY) for the data entry is in the public domain and will remain in the possession of tribes for use in any subsequent surveys.

NPAIHB will prepare a report summarizing the conduct of these surveys and the results of these analyses. We will distribute this report and present the results to each participating Tribal Council, Tribal Health Boards, Tribal Health Directors and their staff, as well as to all delegates of NPAIHB for use in stimulating discussion among health care providers and tribal communities and for guiding the development, targeting, and implementation of prevention programs. In addition, if results from these analyses add new and important information to the general knowledge about health risks and behaviors, NPAIHB will seek, with the participation and approval of all the participating tribes, to publish these results in a reputable, national medical or public health journal to aid other tribal efforts throughout the United States.

Protection of Privacy and Confidentiality

Each potential respondent will be first provided with an explanation of the purpose, general content, and time commitment involved in participating in the survey, and assurances of confidentiality. Each prospective respondent will be given the opportunity to ask any questions at the time of the interview, and will be provided with the name and telephone number of the local contact person who can answer questions before and after the interview is completed. Each potential respondent will be free to decline participation and/or refuse to answer any specific question without any loss of health care benefits or services.

No personally identifying information will be collected during the conduct of the interviews. Furthermore, once interviews are completed and the responses have been verified for completeness and internal consistency, all linkages to home address, telephone numbers and other locating information will be destroyed. Finally, no individual will be identified or identifiable in any report that is prepared based on the data collected as part of these surveys.

All data collected during the conduct of these surveys will be held in the strictest confidence at all times by both the field interview staff and NPAIHB staff. All datasets will be stored on secure, password-protected computers accessible only by authorized staff members (interviewers and site coordinators) of the respective tribes, NPAIHB (Epidemiologist) and CDC/DRH. All hard copy data will be stored in fire resistant, locked file cabinets.

Benefits and Risks

The risks to respondents are limited to the small risk of disclosure of personal information, which is unlikely given the steps that will be taken to protect respondents' privacy and confidentiality, as described above. The likely benefits to the individual respondents are minimal, however, the overall impact for the tribal community will be significant. In addition, the survey results will provide tribes and the NPAIHB with data on their adult members' knowledge, attitudes, and practices regarding cancer and other health-related issues to enhance health promotion and disease prevention programs.

Timeline for the Surveys

No contact with human subjects will be made prior to approvals by the IRBs. In the meantime, sample selection, community preparation, and the hiring of interview staff, will commence as soon as Tribal Councils give their approval and staff can be hired. It is anticipated that community preparation activities will begin shortly after January 2001, and that actual interviews will take place beginning in March-June 2001. A pre-test of the questionnaire will be done before the onset of data collection. The interviews should be completed within a 4-6 month period. Data preparation, analysis, and report-writing should take an additional 2-3 months to complete. Thus, final reports summarizing the results of these surveys should be available for distribution by the end of 2001.

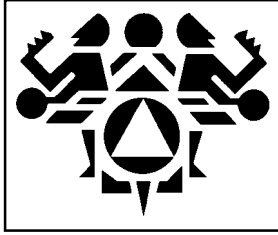
Additional Questions

If respondents have any basic questions regarding the survey, a local contact person will be available in each participating tribe. In addition or alternatively, these questions can be directed to the NPAIHB project staff, Dr. Francine Romero, Epidemiologist, at 1-877-664-0604 (toll free number). All information on contact names and numbers will be provided to respondents during the introductory segment of the interview.

For respondents who have specific questions related to cancer, local coordinators and NPAIHB project staff will answer basic questions, offer to send printed education and informational brochures to respondents, or refer them to the American Cancer Society (1-800-ACS-2345).

Questions regarding rights as a respondent of a research project can be addressed to Dr. Francine C. Romero, Chair, Portland Area Indian Health Service Institutional Review Board, at (503) 416-3286.

Appendix A
Respondent Consent Form



Northwest Portland Area Indian Health Board
527 SW Hall Street, Suite 300
Portland, OR 97201
(503) 416-3286
FAX (503) 228-8182
fromero@npaihb.org

Respondent Informed Consent Form

Purpose and Benefits

The *Tribe's Name* and the Northwest Portland Area Indian Health Board are conducting a survey of current health behaviors with an emphasis on cancer. The purpose of these surveys will be to assess the knowledge, attitudes, and behaviors of adult *Tribe's name* with regard to the prevention of cancer and other health topics. Your participation will help us to identify health needs in our community and to enhance services and programs to improve the health of the *Tribe's name*.

Procedures

We will recruit about 500 adult tribal members 18 years of age and older to participate in the survey. The interview will take about 30 minutes to complete. The interview will include general demographics; health related questions pertaining to cancer, diabetes, hypertension, and, questions on health risk behaviors such as alcohol use, tobacco use, diet and nutrition.

Confidentiality

You will not be identified with the information you give because the survey is confidential. No one but the interviewer and field coordinator will know how you answered questions on the survey. The interviewer has signed a pledge to keep all information about you confidential. Your name will be torn off and a number assigned to the questionnaire. The linked list of names and numbers will be kept in a locked secure place until the questionnaire has been successfully entered into the computer. The identifying information will be destroyed immediately after the data have been entered into the computer and edits run. The questionnaires without your name on it will be destroyed after the data is analyzed. Only project staff will have access to study data. We will not use your name when we report results of the study. The information we collect from you will be combined with information from other Tribal members to help develop a profile of community health behaviors and attitudes.

Risks and Benefits

You may feel uncomfortable with some of the questions we ask on this survey. You can refuse to answer any question you are uncomfortable with or skip questions you do not want

to answer. You can stop the interview at any time. The likely benefits to you are minimal, however, the overall impact for the tribal community will be significant.

Rights as a Volunteer

Your participation in the Health Behavior Survey is voluntary. If you decide not to take part or to stop the interview, you will not lose any services to which you are otherwise entitled.

The law requires that child and dependent abuse be reported. Suspected abusive situations will be referred to appropriate authorities in accordance with tribal law.

If you have any questions about this research project, you may call *the local field coordinator* at *phone number*. You may also call the Principal Investigator, Francine C. Romero, Northwest Portland Area Indian Health Board, at 1-877-664-0604 (toll free number).

If you have any questions about your rights as a respondent, you may call either Dr. Francine C. Romero, Chair, Portland Area Indian Health Service Institutional Review Board, at 1-877-664-0604, or Dr. Clark Marquart, Co-Chair, Portland Area Indian Health Service Institutional Review Board, at (503) 326-7272.

Respondent Agreement

The Health Behavior Survey has been explained to me. I voluntarily consent to participate. I have had an opportunity for my questions to be answered. I know that I may refuse to participate or to stop the interview at any time without any loss of health care benefits to which I am otherwise entitled. I understand that if I have questions about this study or my rights as a respondent, I may contact the local field coordinator or Francine Romero, Principal Investigator.

I understand that as compensation for my participation and completion of the survey I will receive \$10 for my time and contribution.

Respondent Signature

Date

Interviewer Signature

Date

Copies: Respondent Principal Investigator

Appendix B
2001 Northwest Tribal BRFSS Project
Questionnaire

*****Questionnaire Intentionally Not Included in This Model Protocol*****