

# RECRUITMENT AND COMMUNITY INTERACTIONS IN THE GOCADAN STUDY

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## ABSTRACT

**Objectives.** To study heart and vascular disease in Alaskan Eskimos. To identify risk factors for CVD in Norton Sound Eskimos.

**Study Design.** Participatory research. In this paper, procedures for selection and enrollment and providing feedback and referrals are described. Our working relationships with the Norton Sound Health Corporation (NSHC) Board, the village councils, individuals, and communities are also described.

**Methods.** This study was conducted in the Norton Sound region of Alaska. The participants were members of Alaskan Eskimo families.

**Results.** Procedures were formed for selecting and enrolling extended families into the study and for working with the NSHC Board, the village councils, and individual participants. The average participation was 82.6% of the age-eligible villagers in seven villages. A four-level referral system was designed. Test results were provided to participants in the form of letters, with duplicates sent to health care providers and medical records. A senior researcher returned to the village to explain the results to the participants.

**Conclusions.** Principles of participatory research applied and developed in this study led to successful screening of 1214 Eskimos in nine villages between October 2000 and June 2004. This partnership developed into a relationship with the community, in which researchers and the communities mutually participated in the study, from the initiation of the design to the return of the data to the individuals, communities, and health care providers.

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**Keywords:** participatory research, CVD risk factors, Alaska Natives, Inuit, Eskimos

## INTRODUCTION

Climatic conditions and geographic isolation make medical research in Alaskan Eskimo villages challenging. Local villagers' negative experiences with previous researchers and lack of understanding of research and its potential benefits presented additional barriers to study recruitment. In 2000, we began a study of Eskimos living in the villages of the Norton Sound region of Alaska. The Genetics of Coronary Artery Disease in Alaska Natives (GOCADAN) is a study of the contribution of genetics and environment to heart and vascular disease. In this paper, we describe our procedures for selecting, recruiting and enrolling extended families into a genetic study and the process of working with the NSHC Board of Directors, the village councils, and individual participants. We also describe our procedure for providing feedback to the individuals, communities, and village physicians, as well as the health benefits of referrals based on abnormal findings identified during the GOCADAN screenings.

## MATERIAL AND METHODS

### **Working principles, goals, and benefits**

The principles of community health research were established from the beginning of the GOCADAN study. These principles included recognition that successful research depends on community commitment and involvement and that communication and interaction with the communities throughout the study are essential (1-10). Although the goal of the present study is to increase understanding of CVD risk factors in this unique population,

it also afforded the opportunity to provide important health information to individuals, their communities, and NSHC health care personnel. The present study came about as a result of requests from Norton Sound villagers for help in understanding the rapid increase of diabetes and cardiovascular disease (CVD) in their communities and developing strategies for prevention. The GOCADAN study will identify population-specific risk factors that intervention and prevention programs can be developed around. The study was designed in partnership with the Eskimo communities to include extensive communication about needs and expectations. The methods of recruitment and feedback to individuals and communities were based on a mutual understanding of the process described in this paper. This approach is similar to that taken in studies conducted in American Indian communities (11).

### **Reasons for the study and objectives**

Men aged 40 and older in the Norton Sound region have the highest mortality rate of ischemic heart disease (ICD-9 410-414) of the surrounding eight regions (12). A population-based study of stroke incidence in Eskimos found that the majority (79%) of newly diagnosed strokes in Eskimos were ischemic, similar to the rest of the U.S. population (13), but the death rate from stroke in Alaska Natives is 1.5 times the rate for U.S. Whites in general (14). To study the genetic and environmental risk factors for CVD in this population, the present study aimed to enroll 1 200 individuals, aged 18 or older, from nine villages in a cross-sectional setting (15). In June 2004, recruitment stopped with 1 214 participants.

### **The study population**

Evidence suggests that today's Yupik and Inupiaq population in the Norton Sound is fundamentally Asiatic Eskimo, related to the Siberian Yupik indigenous to the Chukotka Peninsula (16-18). Today this population represents an admixture of cultures and language. The Eskimo communities were organized into clans with a strong patrilineal social structure. Hunting and cultural activities generally took place within clans, but marriage often crossed clan boundaries. Little change occurred in this population structure until the late 17<sup>th</sup> century, when contact began with Russian Cossack adventurers, European fur traders, whalers, and Klondike miners. The introduction of the outboard motor in the 1920s added to mobility between villages.

The total population of the Norton Sound region is 9 050, including 7 700 Alaska Natives (2000 U.S. census). Approximately 90% of villages and 54% of people in Nome are Alaska Natives. The Norton Sound is home to about 7 700 indigenous Alaska Natives. Fifteen villages in the region vary in size from 19 to 798 full-time residents. Nome is the supply hub for the region, with a regional airport connecting to Anchorage and Fairbanks. Fourteen of the villages have year-round airstrips connecting them to Nome, but most are not connected by roads.

### **Initiation of the study**

At the request of village elders and after consultations with the NSHC Board of Directors, a grant proposal was approved. The NSHC Board then appointed a Scientific Advisory Board (SAB) to oversee medical research in the region. The SAB includes

members of the full NSHC Board, plus an expert on ethics and human genetics, a staff physician, the CEO of the NSHC (ex officio), and two GOCADAN investigators (ex officio). A representative of the Eskimo community sits on the GOCADAN Steering Committee to keep the investigators aware of the local perspective.

Together with village residents and the SAB, the following operating procedures were developed for recruitment and screening in the villages.

### **Recruitment**

Researchers met with each Indian Reorganization Act (IRA) village council to explain the goals, process, and benefits of the proposed study, and to review the consent forms and rules of confidentiality. After receiving council approval, two investigators visited every household in the village with a locally hired resident who could translate when necessary. The hired residents were often elders recommended by the village council. The information presented to the council was given to each resident, and concerns were addressed to avoid misunderstandings regarding study purposes or logistics. The researchers allotted 30-60 minutes to each household for questions and discussion. All non-pregnant individuals aged 18 and older were invited to participate, so that the data could be used as a cross-sectional assessment for future prospective studies. Participants were asked to provide information about their family relationships, and siblings' villages of residence to facilitate recruitment of these relatives. Full- and half-sibling relationships and adoptive relationships were delineated. When participants stated that a

parent or other close relative's name was not known, or seemed hesitant to provide a name, the interviewer did not pursue that identity, to protect participants' privacy.

In Nome, the screening staff, led by a nurse, did most of the recruiting. Emphasis was placed on recruiting family members of participants already enrolled in the smaller villages. Recruitment results are shown in Table I.

**Table I.** Number of eligible and recruited subjects in 9 villages.

Village	Eligible	Recruited	% Recruited
Shaktoolik	107	83	78
Unalakleet	350	256	73
Koyuk	131	114	87
Elim	141	132	94
White Mountain	97	73	75
Golovin	58	48	83
Teller	117	15	13
Brevig Mission	123	108	88
Nome		384	

The clinic team usually arrived in the village a week or two after the population assessment to carry out the examinations, usually in a house rented through the village council and converted to a clinic. The clinic served as the residence for the examination team, which included a nurse, a technician, and a sonographer hired from the Norton Sound region. One or more local residents were hired in each village to assist in scheduling exams, provide transportation, and administer questionnaires. The exam included 1) questionnaires to obtain medical history, demographic information, health habits, diet (via food frequency), quality of life, and physical activity; 2) physical examination; 3) collection of urine and blood samples; 4) ultrasound measurement of carotid wall thickness and plaques; and 5) electrocardiogram. Details of the methods for

the examination and measurements have been published previously (15).

### Access to medical records

Permission to access records was sought both at the NSHC level and from individual participants. The Indian Health Service contracts out all medical care for the villages in the Norton Sound region to the NSHC, which operates the Norton Sound Hospital in Nome, a 19-bed acute-care hospital with a large outpatient facility. Patients requiring tertiary care are flown to the Alaska Native Medical Center in Anchorage. NSHC also operates small health clinics in each village. This centralization of services greatly simplifies surveillance of morbidity and mortality records in the present study.

### Individual guidance based on test results

The following procedure was used to provide test results to the participants and their health care providers.

During the medical exam, participants received information about their hemoglobin and glucose levels, a preliminary review of their ECG results, and educational materials about a heart-healthy lifestyle. The examining personnel also educated participants about the importance of risk factor reduction and specific modifications that might reduce their risk for cardiovascular disease. Abnormal test results were referred to NSHC providers based on the guidelines detailed in Table II. Individual results were relayed as soon as available to the participant.

As blood and urine samples were being analyzed, the laboratory called the GOCADAN supervisor in Nome whenever a measurement met the alert criteria shown in Table II.

**Table II.** Referral guidelines at the time of the examination.

Type of referral	Physician visit scheduled within	Indications	Actions
Emergency	Immediately	Systolic BP > 260 mmHg Diastolic BP > 130 mmHg Abnormal ECG or acute cardiac symptoms Symptom suggesting life-threatening angina or pulmonary edema	Refer to village paramedic personnel Phone/radio Nome NSHC physician Air evacuation if needed
Immediate	1 day	Fasting glucose > 22.2 mmol/L Systolic BP 200-259 mmHg Diastolic BP 105-129 mmHg Diabetic foot ulcer Angina in last day Neurologic symptoms in past week Carbon monoxide reading > 125	Notify participant's physician or NSHC Arrange for appointment and transport Provide NSHC referral
Urgent	1 week	Suspected congestive heart failure Inappropriate medication use Accu-Chek fasting glucose > 11.1 mmol/L (absent diabetes) Active TB symptoms Carbon Monoxide reading 20-124 (non-smoker) or 50-124 (smoker) Untreated neurological symptoms 1 week to 6 months ago	Arrange for appointment and transport Provide NSHC referral
Routine	1 month or first convenient	Systolic BP 140-199 mmHg Diastolic BP 90-104 mmHg Old MI (Rose Questionnaire) Previously unrecognized neurological problem (i.e., stroke) Previously unrecognized claudication Both pedal pulses missing in one extremity Doppler ankle/arm pressure ratio < 0.8 Hemoglobin < 100 g/L (women) or < 120 g/L (men)	Arrange for appointment and transport Provide NSHC referral

TB = tuberculosis; MI = myocardial infarction

This was considered an urgent referral and the procedures shown in Table II were followed. When laboratory measures were completed, the GOCADAN Coordinating Center for the study mailed a letter to each participant with his or her results and explanations of the test results. Concurrently, the coordinating center prepared a spreadsheet of all participants and their results and sent it to Nome. The Field Administrative Manager in

Nome forwarded a spreadsheet of all results to the physician designated as liaison to the research program by the NSHC. The physician then determined what actions should be taken by the NSHC staff.

After the exam team completed a village, a senior GOCADAN investigator returned to the village to explain the results to individuals and the overall findings in community meetings with the village council.

Unconfirmed, machine-generated, ECG reports were available at the exam. ECG findings requiring immediate review by a physician were transmitted by fax to a physician before the participant left the clinic and included:

a. Acute pattern abnormalities: Myocardial infarction, ischemia, injury, subendocardial ischemia, or pericarditis.

b. Rhythm disturbances: 2<sup>nd</sup> or 3<sup>rd</sup> degree block, ventricular tachycardia, supraventricular tachycardia, atrial fibrillation or flutter with a ventricular rate < 60/min, or > 110/min, atrioventricular junctional rhythm, sinus bradycardia < 40/min, sinus tachycardia > 110/min, or PR interval > 0.26 sec.

c. Any other ECG findings, alone or in conjunction with symptoms, causing concern.

Other ECG findings to be reviewed the same day, if possible, included those with QT prolongation. ECGs for which routine referral was usually appropriate included those with a new left or right bundle branch block, Wolff-Parkinson-White syndrome (ventricular pre-excitation), left ventricular hypertrophy, or new Q-wave myocardial infarction. Confirmed reports were available for all ECGs after they had been reviewed by a physician at the Cardiology Reading Center at Cornell University.

For carotid ultrasound exams, the Cardiology Reading Center called the

**Table III.** Number of referrals.

Laboratory test	Value	Number and %
Fasting glucose	< 2.2 or > 22.2 mmol/L	0/953 (0%)
Total cholesterol	> 7.8 mmol/L	16/950 (1.7%)
Triglycerides	> 11.3 mmol/L	1/950 (0.1%)
Urine albumin/creatinine	> 300	5/920 (0.5%)
TSH	< 0.4 or > 4.0 mIU/L	94/951 (9.9%)
Cholesterol	> 5.2 mmol/L	474/950 (49.9%)
LDL cholesterol	> 3.4 mmol/L	308/950 (32.4%)
HDL cholesterol	< 1.0 mmol/L	94/950 (9.9%)
Triglycerides	> 2.3 mmol/L	120/950 (12.6%)
Hemoglobin A1C	< 4.4 % or > 6.5 %	17/952 (1.2%)
Urine albumin/creatinine	> 30	55/920 (6.0%)
Fasting glucose	< 3.3 or > 6.1 mmol/L	62/953 (6.5%)
Systolic BP	140-199	97/1021 (9.5%)
Diastolic BP	90-104	67/1021 (6.6%)
Hemoglobin, women	< 100 g/L	22/538 (4.1%)
Hemoglobin, men	< 120 g/L	36/421 (8.6%)
<i>Carotid Ultrasound Results</i>		
Normal		622/939 (66.2%)
Non-obstructive narrowing		309/939 (32.9%)
Significant narrowing		5/939 (0.5%)
Severe narrowing		3/939 (0.3%)

Field Administrative Manager at the hospital in Nome if > 50% obstruction was noted in the carotid artery. Participants received an immediate referral if the obstruction was > 75%, a routine referral if the obstruction was between 50 and 74%, and a referral for risk factor assessment if the obstruction was < 50%. All participants received a letter with an explanation of their results and suggestions for exercise and a healthy diet.

### **Group discussions and communication**

A GOCADAN investigator presented study progress and results at the quarterly SAB meetings. That information also was presented to the full NSHC Board. In addition, at least one study Steering Committee meeting, and multiple site visits, were held in Nome, with accompanying visits to the villages, so investigators could have a chance to meet with NSHC staff and community leaders and residents, to introduce themselves, establish personal relationships, discuss the conduct of the study, and share their perspectives on issues relevant to the research. For example, on one visit, senior investigators went to the NSHC in Nome to adjudicate cardiovascular events reported by participants using medical records. The investigators took the time to present a progress report to the SAB and take in the beauty of the tundra while meeting the villagers of Teller. A biannual newsletter describing the progress of the study and results in lay language is mailed to participants. These newsletters can be viewed at the study website, <https://www.sfbr.org/gocadan.secure/public/newspart.html>.

## **RESULTS**

### **Recruitment**

Table I shows recruitment by village. Study participation in the various villages was about 80%, with two exceptions. More than 95% of age-eligible villagers agreed to participate at the time of the recruitment and household survey, but a smaller number actually participated, either because they were away from the village during the screening, or because of time conflicts. Of the approximately 5% who refused to participate, reasons given included fear of needles, length of exam, too old, homebound or frail, distrust of staff, or influence by another family member.

### **Referrals**

Referral guidelines are shown in Table II, with numbers of referrals shown in Table III. There were no emergency referrals, four immediate referrals for elevated diastolic blood pressure, and four urgent referrals (one for elevated fasting glucose, one for elevated carbon monoxide [CO] in a non-smoker, and two for elevated CO in a smoker). Clinical alerts, determined by the laboratory staff when processing specimens, occurred in 2.3% of participants. Most participants had normal carotid scans, and about one-third had non-obstructive narrowing of the carotid arteries. Fewer than 1% had significant or severe narrowing. Many participants were helped directly by the GOCADAN exam, which resulted in the discovery of health problems the participants did not know they had, including 68 cases of hypertension, 10 cases of diabetes, and 186 cases of high cholesterol levels.

## DISCUSSION

Thirty years ago, diabetes and CVD were rare among Alaskan Eskimos (19). Mortality from ischemic heart disease (ICD-9 410-414) for men in the Norton Sound region is now twice that of neighboring populations.(12) The current death rate from stroke among Alaska Natives is 1.5 times that in the U.S. White population (14), and the prevalence of diabetes (a major risk factor for CVD) is increasing rapidly (20). The rising prevalence of diabetes and CVD has baffled the Eskimos. Without newspapers, and with TV only in the last few years, minimal health information has been available. Few formal prevention programs on diet and physical exercise are available in the Norton Sound region. Hence, there is much interest in the research and the explanations researchers have provided.

The GOCADAN study builds on the experience of the Alaska-Siberia Project (20), a study on diabetes prevention in other Norton Sound villages, which preceded the present study. Some of the current researchers participated in that previous study. We learned that, in order to recruit effectively, the researchers need to work closely with the villagers, not by infrequent casual visits, but by house-to-house familiarization with their lifestyle and by learning what behaviors or practices might be undermining their health. During the present study, we spent time visiting the households and explaining the study. Some of the villagers welcomed the research team with Eskimo dancing, traditional meals, invitations to church services and bingo, ice fishing, and endless cups of coffee.

Recruitment varied by village and largely depended on seasonal activities in the

community. Recruitment during the summer was less successful, because village residents were frequently unavailable because of 1) fishing activities, 2) hunting, or 3) gathering greens and berries. In the village of Teller, it was not feasible to continue recruitment during the summer, when community members were away fishing, so the clinic field team closed that clinic and visits to other villages prevented their return. They had more success with the clinic in Nome during the summer, where individuals are somewhat less dependent on seasonal subsistence activities. Other diversions exist in Nome, however, including full-time jobs and more social activities. In addition, health care is more accessible in Nome and the physical exam that was part of the study was less of an incentive to participate in Nome than in the villages. The highest recruitment rates were achieved in two villages where relatives of people involved in the initial GOCADAN study lived. Residents of these villages may have had more knowledge of the study and its importance, and peer pressure may have encouraged their participation. The high recruitment rate in a third village may have been due to the use of two recruiters: one worked in the clinic most of the time, making phone calls, and the other visited households and provided transportation to the clinic. The study team has a four wheeler for transporting participants to and from the clinic.

We also learned that the villagers wanted feedback and communication from the researchers. The villagers told us that many researchers had come to the village, collected blood samples and other data, and then were never heard from again. In the present study, an investigator returned to each village with

the results, spent time with the village councils and the families in an informal and friendly atmosphere, and asked questions about Eskimo life. We also referred participants to health care providers when abnormal conditions were found.

Most of the referrals at the time of the examination were for elevated blood pressure, while most of the laboratory clinical alerts were for elevated total cholesterol. Both of these risk factors for CVD can be controlled by diet, exercise, and medication. Many participants had laboratory values, especially for lipids, that were outside of the normal range and were referred for routine follow-up. Although these abnormal values might not cause the participants health problems now, they are risk factors for CVD.

The current study has begun to contribute to the prevention of disease by identifying modifiable risk factors that were unknown in the population. This is the first and immediate benefit of GOCADAN. The villagers are acutely aware of increases in diabetes and CVD, but often have no understanding of what has caused the increases. We have told them that, as researchers, we are interested in helping them identify the reasons and develop solutions. We have emphasized that research to identify ethnic-specific risk factors is needed to launch effective prevention programs. We are currently helping to develop a smoking cessation program in the Norton Sound region. The Diabetes Prevention Program of the NSHC, partially based on the research results of the GOCADAN study, has started and activities are underway to develop additional intervention programs to increase physical activity and weight reduction and to improve diets. The latter project

will focus on the reduction in consumption of saturated and trans fats, which is exceptionally high in this population (21).

### Conclusions

The success of an epidemiological study depends on establishing good, often personal, relationships with the participants. This is especially true when working with groups who have had negative experiences with investigators who lacked cultural sensitivity and failed to provide feedback or useful information to individuals and their communities. The GOCADAN study evolved from requests by the Native communities for help with their growing prevalence of diabetes and CVD. Over time, a good relationship has developed and a mutually beneficial partnership has evolved.

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