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TITLE: Alaska Native Parkinson's Disease Registry

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14. ABSTRACT This registry initiates a program of epidemiological assessments of PS among Alaska Natives to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Natives may be estimated as well. This registry not only would facilitate future research into PS etiology, but also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population. The registry is designed in two phases. Phase 1 is a developmental period and is well underway at this time. During this phase, we established the data collection and dissemination protocols, regulatory submissions are under review for the registry to obtain necessary approvals, the registry database is under development and a pilot project in Anchorage will be initiated pending approvals. Phase 2 has not yet begun. It is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.					
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A. Introduction

Parkinsonism (PS) is a syndrome characterized by tremor, rigidity, slowness of movement, and problems with walking and balance. Parkinson's disease is the most common form of PS, accounting for about 1% of the U.S. population over age 50 years. Little information is available about trends in PS, particularly in Alaska Natives.

This registry initiates a program of epidemiological assessments of PS among Alaska native people to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period that is currently ongoing. During this phase, data collection and dissemination protocols are being established, necessary approvals for the registry are being obtained, and a pilot project in Anchorage will be initiated following approvals. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.

B. Body

The aims of this registry project remain unchanged:

1. Surveillance - Identify all cases of PS among AK Native people and develop an electronic registry database.
2. Broadly characterize the clinical features of PS among AK Native people
3. Identify factors influencing the clinical care and management of individual with PS and disease progression
4. Provide education on PS and its treatment to primary care physicians, other health care providers, patients, and caregivers

Through these aims, the registry initiates a program of epidemiological assessments of PS among Alaska native people to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is ongoing in the same population.

The registry is designed in two phases. Phase 1 is a developmental period that is currently ongoing. During this phase, data collection and dissemination protocols are being established, necessary approvals for the registry are being obtained, and a pilot

project in Anchorage will be initiated following approvals. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center (ANMC).

Phase 1 activities have taken longer than anticipated due to many challenges faced in obtaining regulatory approval to initiate data collection. We originally anticipated phase 1 activities would take a year to complete. However, that assumed that only 1 protocol would be developed and submitted and that the regulatory review would take at most 4 months. The initial regulatory review in Anchorage for each protocol actually takes 10-12 months including review by the AK Area IRB, privacy officers, the 2 tribal boards in Anchorage and then final review by the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office.

At the suggestion of a representative of the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office, the current strategy is to develop 4 independent protocols, 1 for each of the specific aims. This approach is expected to better clarify the aims and satisfy the requirements of the individual agencies but will also require more time for submission, approval and implementation. The current protocol for specific aim 1, surveillance (limited to Anchorage) and the development of the electronic registry database, has been under review by the AK Area IRB since February 2009. While the AK Area IRB has given a preliminary approval, the final approval is contingent upon review by the privacy officers in Anchorage. Review by the privacy officers is currently in progress (September-November, 2009) Upon approval by the privacy officers, the protocol will be passed on to the 2 tribal boards in Anchorage and then on to the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office for final approval. Once the protocol for aim 1 is approved by all for initiation in Anchorage, the 3 remaining protocols will be submitted via the same process. To do this, we requested and received an extended period of performance through Nov 2011. The following milestones were modified to reflect the additional work required for the project and were also approved.

SCOPE OF WORK

Phase 1, Development and Pilot Study:

To efficiently conduct the proposed work, a development phase is necessary. First, culturally sensitive methods and educational materials specific to the Alaska Native communities must be developed. Second, this work will not be possible without gaining the support of the tribal organizations. Once both of these are accomplished, the registry must be pilot-tested. The development phase will allow these aims to be achieved, helping to assure a successful and efficient registry. The specific tasks for this phase will include:

1. Establishing the scientific steering committee. Complete

2. Developing an identification protocol. The primary source of parkinsonism cases will be the Indian Health Service (IHS) provider database, called the Resource and Patient Management System (RPMS), but the protocol will include identifying other possible sources that would identify other cases of parkinsonism among Alaska Natives. Complete
3. Developing a secure Alaska Native parkinsonism registry database. Expected completion February 2010. While the database has been designed, the final programming will be postponed until approval from all regulatory bodies can be obtained (i.e., the Alaska Area IRB (the IRB for the Anchorage service unit), Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office).
4. Ascertaining needs and interests of the Alaska Native community with regard to the parkinsonism registry project. The initial survey of needs and interests within the Anchorage service unit is expected to be complete in March 2010
5. Developing a preliminary proposal for review by Alaska Native tribal organizations. Subsequent more detailed versions of the protocol will be submitted for review as they are developed as well. The original scope of work called for the development of 1 protocol that covered all 4 aims of the registry project. The U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office suggested that we develop and submit 4 separate protocols, 1 for each specific aim.
 - a. SA1: Surveillance - Identify all cases of parkinsonism among Alaska Native people and develop an electronic registry database.
 - i. Protocol development and submission to the Alaska Area IRB— Is Complete – Submitted February 2009 to the Alaska Area IRB. Final approval is pending review by Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office.
 - b. SA2 - Broadly characterize the clinical features of parkinsonism among Alaska Native people
 - i. Protocol development and submission to the Alaska Area IRB – Expected submission January 2010.
 - c. SA3 - Identify factors influencing the clinical care, disease progression and management of individuals with PS.
 - i. Protocol development and submission to the Alaska Area IRB – Expected submission January 2010.
 - d. SA4 - Provide education on parkinsonism and its treatment to primary care physicians, other health care providers, patients, and caregivers
 - i. Protocol development and submission to the Alaska Area IRB – Expected submission March 2010

6. Establishing appropriate infrastructure and personnel in Alaska. Expected completion November 2009. The hiring of registry abstractors is currently postponed until all regulatory approvals are obtained for the Anchorage service unit.
7. Developing detailed data collection and management procedures. Expected completion February 2010. Preliminary data collection and management procedures have been developed. The details of the management procedures will be modified as necessary in combination with the development of the electronic database which is expected to be finalized February 2010.
8. Developing detailed medical records abstraction protocols for data on clinical features, comorbid conditions, clinical management, and factors possibly affecting clinical management (e.g., home environment). Expected completion is February 2010 in combination with the finalization of the electronic registry database.
9. Working with communities to develop a multilevel educational program for health care providers, patients, and caregivers, addressing parkinsonism identification and management Expected completion June 2010 for the Anchorage service unit.
10. Refining the study protocol and preparing the operations manual. Expected completion February 2010 in combination with the finalization of the electronic registry database.
11. IRB approval and Alaska Native tribal organization feedback on and approvals of final protocols.
We will submit 4 separate protocols and receive approvals to begin work in Anchorage for each specific aim.
 - a. SA1: Approval from the Alaska Area IRB, Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office – Expected Dec 2009
 - b. SA2 - Approval from the Alaska Area IRB, Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office – Expected Sept 2010
 - c. SA3 - Approval from the Alaska Area IRB, Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office – Expected Sept 2010
 - d. SA4 - Approval from the Alaska Area IRB, Anchorage privacy officers, 2 Anchorage tribal boards and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office – Expected November 2010

12. Pilot registry project among Alaska Natives residing in Anchorage Service Unit. Expected completion March 2010.
13. Initial implementation of educational program. Expected initiation will be November 2010.
14. Monitor quality and completeness of registered data, and define data collection challenges. The expected initiation of quality checks is February 2010 when we anticipate approval by the final regulatory agency for data collection in the Anchorage service unit.

Phase 2, Registry Implementation:

When the tasks of the development phase have been completed in Anchorage, we will expand the collection of parkinsonism registry data to Alaska Natives statewide. The specific tasks for this phase will include:

1. Abstracting information from medical records of prevalent and incident parkinsonism cases into the parkinsonism registry statewide. Prior to statewide abstraction, regional board approval must be sought in 10 regions.
 - a. Regional, tribal board submissions are expected to be completed May 2010
 - b. Regional, tribal board and U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office approvals are expected to be completed October 2010 if revisions are not requested by the boards.
 - c. Statewide abstraction will be phased in as regional tribal board approvals are received and the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office gives a memorandum of acceptance for each region.
2. Continuing implementation of educational program for health care providers, patients, and caregivers. Expected to begin in regions November 2010 and continue for the duration of the registry.
3. Reporting, analysis and publication. Initial results and analyses from the Anchorage service unit are expected November 2010. Statewide results and analyses are expected by November 2011.

C. Key Research Accomplishments

- Requested and were awarded revisions to the period of performance through Nov 2011 and modifications to the statement of work.
- Met with collaborating neurologists in AK, other local investigators, and Parkinson's Institute staff to refine approach for achieving regulatory approval for all 4 specific aims.
- Interactions with the Alaska Area IRB representatives, a compliance reviewer at the DOD to revise the protocol, and several on going iterations with the privacy officer at the Alaska Native tribal Health Consortium.
- Revised submission of the registry protocol to the AK Area IRB.
- Continued revisions to registry abstraction tool and protocols to satisfy the requests of the reviewers.

D. Reportable Outcomes

While many milestones of phase 1 of this project were met, we are still in the process of obtaining approvals necessary to begin data collection. Until this has been accomplished and state wide data has been collected, we will not have reportable outcomes.

E. Conclusions

Phase 1 of this project is well underway. We have encountered challenges in determining an appropriate and efficient course for satisfying the regulatory needs for this project although we now have agreement with the reviewers to submit 4 separate protocols in sequence. Following the completion of state wide data collection (Phase 1 and 2) and analysis, it will be possible to draw relevant scientific conclusions.

F. References

None

G. Appendices - Alaska Native PS Registry IRBs and Tribal Boards

Table 1. Institutional Review Boards

Institution	Review Board	Status
Parkinson's Institute	Western Institutional Review Board (WIRB)	Submission pending
Alaska Native Medical Center	AK Area IRB	Approved pending Privacy consult
Pacific Health Research Institute	VA Pacific Islands Health Care System	Submission pending
US Army Medical Research and Material Command	Office of Research Protections	Submission pending

Tribal board contacts within Anchorage basin:

1. Southcentral Foundation (SCF) (Anchorage)
2. Alaska Native Tribal Health Consortium (ANTHC) (Anchorage)

Regional Tribal board contacts outside of Anchorage:

Tribal health organization	Contact name	Contact e-mail
Maniilaq Association	Roger Johnson	roger.johnson@maniilaq.org
Maniilaq Association	Ian Erlich	ierlich@maniilaq.org
Maniilaq Association	Robert Gibson	robert.givson@maniilaq.org
Alaska Native Health Board	Evangelyn Dotomain	edotomain@anhb.org
Southeast Regional Health Consortium	Lincoln Bean, Sr.	lbean@me.com
Tanana Chiefs Council	Andrew Jimmie	ajimmie@hotmail.com
Norton Sound Health Corporation	Emily Hughes	emily@stargatealaska.com
Yukon Kuskokwim Health Corporation	Bill Kristovich	donna_gibbons@ykhc.org
Kodiak Area Native Association	Heather Parker	heather.parker@kanaweb.org
Bristol Bay Area Health Corporation	H. Sally Smith	ssmith@bbahc.org
Arctic Slope Native Association	Marie Carroll	marie.ahgeak@arcticslop.org
Ketchikan Indian Community	Cecelia Johnson	cecelia34@hotmail.com
Metlakatla Indian Community	Burley Wellington	burley@ptialaska.net