Award Number: W81XWH-07-1-0261

TITLE: California's Parkinson's Disease Registry Pilot Project – Coordination Center and Northern California Ascertainment

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REPORT DATE: March 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
1 Mar 2009	Annual	1 Mar 2008 – 28 Feb 2009

4. TITLE AND SUBTITLE

California's Parkinson's Disease Registry Pilot Project – Coordination Center and Northern California Ascertainment

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-07-1-0261

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Parkinson's Institute
Sunnyvale, CA 94085

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The primary goal of this project is to conduct a pilot study for the legally mandated population-based Parkinson's disease (PD) registry in the state of California. This study is one of two linked research programs with the goals of establishing and using California PD registry data. The Parkinson's Institute was funded to serve as the coordinating center for the pilot project (including maintaining a secure data enclave), conduct ascertainment work in Santa Clara County and initiate research with the nascent registry. Case ascertainment in three target southern California counties (Kern, Tulare and Fresno) and exploratory research is being done by the University of California Los Angeles. To date, a total of approximately 1,981 parkinsonism cases have been identified in Santa Clara County via legally mandated reporting sources, including physicians and health care facilities. As case finding work continues, research work will soon be initiated, to investigate possible associations between PD and toxicant exposure using state databases, to assess the value of the registry to stakeholders and to evaluate cost-efficient strategies for registry operations.

15. SUBJECT TERMS
Parkinson's disease, disease registry, active case ascertainment, prevalence

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	6	19b. TELEPHONE NUMBER *(include area code)*

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A. Introduction

This project consists of a pilot study conducted in partnership with the California Department of Public Health (CDPH) and the University of California-Los Angeles School of Public Health (UCLA) to implement a legally mandated statewide population-based Parkinson's disease (PD) registry in California to serve health surveillance and research aims. As the coordinating center for the surveillance activities, the Parkinson's Institute has achieved multiple milestones, including the development of data collection tools, staff training materials, a secure database, and policies and procedures for registry operations. Case ascertainment activities by the PI and UCLA have been underway in the four target counties in northern and southern California for six months, with approximately 4,249 PD cases identified to date from legally mandated reporting sources. As the database grows, the next priorities are to implement systematic de-duplication procedures to ensure unique entries, to validate the registry content (i.e. confirmation of diagnosis and other qualifying criteria) and assess the efficiency of data collection approaches. As these objectives are reached, the research aims of the project can then be addressed: assessing differences in PD incidence and patterns of care across different groups, explore possible associations between toxicant exposure and PD patterns utilizing state hazardous substances databases, determine the value of the registry to key stakeholder groups, and perform a cost analysis.

B. Body

The goals of this research are to conduct a feasibility study for the legally mandated California statewide population-based PD registry and utilize pilot registry data to explore trends in PD prevalence, patterns of care, possible relationship to the distribution of environmental toxicants, stakeholder priorities and cost efficiency of operations. This project is linked with a USAMRMC-funded project based at UCLA (Award Number W81XWH-07-1-0005, Principal Investigator: Beate Ritz), under which case ascertainment in southern California and exploratory research is being performed.

The initial phase of this project has involved the establishment of a secure, high quality registry database, under the authority of the CDPH. The specific tasks related to this health surveillance activity were initiated in the first project year and have been advanced substantially in the second year. The first project phase encountered significant delays, as detailed in the application for a no-cost extension, submitted and approved last month (copy of request and approval attached). With the ascertainment methods and database are now well established, and a substantial number of cases registered, the project will transition to addressing its stated exploratory research aims.

C. Key Accomplishments

Task 1: Obtain deputization status from the CDPH as designated agents for creation of the registry. contracts between CDPH and PI were finalized and signed in October, 2007.

Task 2: Obtain approval from Institutional Review Boards. Human subjects research waivers for this initial work was obtained from the Army Medical Research and Materiel Command Office of Research Protections Human Research Protection Office, the State of California Committee for the Protection of Human Subjects (CPHS), the Kaiser Permanente Northern California Institutional Review Board and the UCLA Office for Protection of Research Subjects. A new application has been filed with the CPHS seeking approval to link registry data with Medicare

data from the Center for Medicare and Medicaid Services (CMS), in order to initiate a validation and efficiency study of the registry database utilizing capture-recapture analytic methods.

Task 3: Notify case reporting sources and professional organizations of registry implementation, as required by the California Parkinson's Disease Registry Act. A formal notification letter was developed in conjunction with CDPH, and mailed in January 2008 to the state Medical Board and the Board of Pharmacy, professional organizations representing potential case reporting sources (pharmacists, physicians and health care facilities) and public health officers in the project target counties.

Task 4: Conduct outreach to stakeholders. A public stakeholders' meeting was convened in March, 2006. A free-standing website (www.capdregistry.org) was created and launched in March, 2008. A public fact sheet and informational brochure were developed and have been utilized in mailings and at patient-oriented events.

Task 5: Convene a Stakeholders' Advisory Committee. Under the direction of its leaders, Mr. Greg Wasson, Ms. Anne Wasson and Mr. Mark Siegel, a committee is acting to create a forum and network in which registry stakeholders can be informed of project activities, and provide input to the project.

Task 6: Define case ascertainment strategies. Investigators at the PI and UCLA initiated case ascertainment activities by approaching physician offices (neurology practices in particular) and medical groups, to enhance the willingness of these high-yield sources to cooperate with the reporting requirements. Ascertainment efforts will be extended to large health care facilities and institutional pharmacies in the near future, and a patient self-registration process will be activated.

Task 7: Create tools for data collection.
A data collection form and Microsoft Access database was developed and pilot-tested by staff (both physicians and non-physicians) at the PI. The form includes fields for obtaining information on basic demographics, key clinical parameters and characterization of data collection feasibility.

Task 8: Develop policies and procedures for ensuring data confidentiality, quality and appropriate use. Policies and procedures have been developed, together with staff training materials. PI and UCLA project employees attended two group training sessions in September and October, 2008. A secure, non-networked data repository was established in a dedicated room with access limited to trained project personnel. With the launch of field data collection in October, 2008, weekly conference calls have been held to keep all staff updated on progress and the latest standard operating procedures on safe data collection/transmission and storage.

Task 9: Initiate data collection. Registry staff were hired and trained in communication with potential reporting sources as well as specific project security procedures. The data collection accomplishments during year two, from October, 2008 through March 2009, are shown in the Reportable Outcomes section. The table shows the number of patients reported to us (prior to systematic de-duplication). Initial efforts have focused on the collection of basic identifying and demographic data, by direct record abstraction if not available directly via a provider report. Data collection will be expanded to collect more detailed clinical information on a subsample of cases for diagnosis validation purposes.

D. Reportable Outcomes

Number of Reported PD Cases, October 2008 through March 2009

	Northern CA Ascertainment (PI)	Southern CA Ascertainment (UCLA)		
County	Santa Clara	Fresno	Kern	Tulare
Physician Offices Contacted	30	18	10	8
Medical Groups Contacted	76	0	0	0
# of Patients Reported	1,1981	1,096	885	287
Total # of Patients Reported	**1,981**	**2,268**		

E. Conclusions

Since our last annual progress report, most milestones in the project's primary specific aim ("Develop the best method for active ascertainment and registration of cases with PD and parkinsonism") have been achieved. Establishment of the registry now enables us to address the remaining research aims of the project. Important next steps for the project include the following:

1. Apply systematic de-duplication methods to ensure unique entries in registry database, as multi-source case ascertainment efforts continue.
2. Finalize training materials and sampling approach for more detailed clinical abstraction work.
3. Submit application to CMS for Medicare data, to be used in capture-recapture validation analysis
4. Activate voluntary patient self-reporting procedure.
5. With Stakeholders' Advisory Committee, continue outreach and assess value of registry to stakeholders.
6. Finalize plans for additional research aims of analyzing patterns of PD incidence and care, exploring possible associations between toxicant exposure and PD and undertaking a cost analysis of registry operation.

F. References

None.

G. Appendices

None.