



THE CALIFORNIA PARKINSON'S DISEASE REGISTRY: FACT SHEET

What is the California Parkinson's Disease Registry?

The California Parkinson's Disease Registry Act, signed into law by Governor Arnold Schwarzenegger in late 2004, makes Parkinson's disease (PD) a reportable condition, and requires the state health department to establish a database listing people who have Parkinson's disease (California Health and Safety Code Sections 103860-103865). This new PD Registry will join a list of other state databases (such as the California Cancer Registry) designed to track important diseases and public health hazards.

What is the purpose of the Registry?

The legislation was passed to improve knowledge about the causes and treatment of PD. Surprisingly little is now known about how common this condition is among different population groups, what the causes are, and whether the patterns of disease are changing over time. Collecting and analyzing this information in a large and diverse state like California will provide important clues about the causes of the disease, as well as help to ensure that adequate health care resources are available for all patients.

Has the Registry started yet?

Although the Registry Act mandates the creation of a statewide Registry, the expense and complexity of this endeavor mean that the project will be developed in several stages over time. The first phase of the project that is now being launched is a Pilot Program. The Pilot Project will develop a PD Registry in four California counties (Santa Clara, Fresno, Kern and Tulare) designated by the California Department of Public Health (CDPH) as reporting areas. The goals of the Project are to establish the basic framework for the Registry operations, and to determine the most efficient ways of gathering information, over a two to three year period. This work will ensure that the Registry database is secure and of high quality, and that the Registry can be maintained over time and expanded to other areas of California in a cost-efficient way.

Who will be in charge of the Registry Pilot Project?

The Pilot Project will be carried out by the CDPH in conjunction with two partners, The Parkinson's Institute (a not-for-profit clinical and research organization in Sunnyvale) and the UCLA School of Public Health. These partners were selected for the project based on their extensive experience in PD-related research. In addition, the Project leaders will be guided by input from a Scientific Advisory Committee and a panel of stakeholders including patients and advocacy groups.

How is the Registry funded?

The Registry Act did not provide state funds to support the creation of the Registry. In recognition of the value of developing a PD Registry, funding for the Pilot Project is being provided by the Michael J. Fox Foundation for Parkinson's Research, the National Institute of Environmental Health Sciences and the US Army Neurotoxin Exposure Treatment Research Program. Additional support is being sought from other sources.

What kind of data will be collected?

For the Pilot Project, Registry staff will be collecting demographic information about persons with PD (e.g. name, birthdate, address), their health care providers (e.g. physician specialty) as well as basic clinical information (e.g. date of diagnosis, medications, disease features). All data will be collected and stored using state-of-the-art procedures and technology designed to protect the confidentiality of registered individuals. These procedures have been developed and utilized by other health department registries over several decades without security breaches.

Who will be required to report?

The Registry Act requires physicians/surgeons, pharmacists, other health care practitioners as well as hospitals, health care facilities and other agencies diagnosing and treating PD patients to report their cases and allow access to their records by authorized Registry staff. Willful failure to grant this access is punishable by a civil penalty of up to \$500 each day access is refused.

How will the Registry data be collected?

For the Pilot Project, an "active case ascertainment" approach will be taken. Trained Registry Pilot Project staff will be contacting and visiting facilities where PD care is provided to collect information on individual cases. Some of this data will be available in established electronic databases maintained by the clinical and pharmacy institutions. In other cases, project staff will obtain case information directly from other sources such as medical records. In response to interest expressed by the PD community, there will also be a mechanism for patients to voluntarily self-register.

What about HIPAA and patient confidentiality?

As a public health surveillance project mandated by state law, the Registry is permitted under HIPAA to obtain identifying and other medical data without obtaining informed consent from individual patients.

As noted above, maintaining strict confidentiality is a high priority of the Registry. Following applicable state and federal laws and detailed procedures previously

established for other state health registries, all data will be managed with encryption protection and stored in a secure database. A limited number of trained Registry staff will have access to the data for purposes of maintaining the Registry and creating summary public health reports, and will be required to adhere to strict security procedures.

How will the Registry data be used?

The Pilot Project data will be analyzed to look at the trends of PD in the four county zone. Reports summarizing Registry data will be published, but under no circumstances will any identifying information (patient, provider or facility) be released in these reports.

In the future, Registry data may in the future be shared with researchers who are investigating PD-related issues such as risk factors and health care patterns. For any researcher to be permitted access to any Registry data they will be required to adhere to strict data security procedures and guidelines for research to be developed by the Registry's Scientific Advisory Committee. In addition, no Registry data will be released until the researcher has obtained approval for that specific research project from the California Committee for the Protection of Human Subjects and their own institutional human subjects research committee.

Where can I get more information?

Updated information about the Registry is available at www.CAPDRegistry.org. Also, you may send your questions via email to: CAPDRegistry@theipi.org.