MASSACHUSETTS PARKINSON'S DISEASE REGISTRY ADVISORY COMMITTEE

May 30, 2022

Final Report

Table of Contents

Introduction

This report is a compilation of work conducted by the Massachusetts Parkinson's Disease Registry Advisory Committee. The committee was established through a legislative mandate to establish a Parkinson's Disease Registry in Massachusetts.[1] The committee was established in November of 2021 by the Massachusetts Department of Public Health (MDPH). Recruitment and appointment of members began in early December 2021. The statutory language specifies the committee membership as "The committee shall consist of the commissioner, or a designee, and 10 members to be appointed the commissioner as follows: 3 physicians, 1 of whom shall be a general neurologist, 1 of whom shall be a movement disorder specialist and 1 of whom shall be a primary care physician; 1 health informaticist; 2 population health researchers familiar with registries; 2 Parkinson's disease researchers; and 2 persons diagnosed with Parkinson's disease. The MDPH was challenged to find any population health researchers familiar with registries to commit to participation on the committee. Therefore, the committee work presented in this report reflects the work of a 9-member committee. The committee met several times between January 2022 and May 2022. The meeting schedule and meeting information are listed on the MDPH website.[2]

Committee Membership

Parkinson's Disease Researcher
- Committee Chair: **Cathi A Thomas**, MSN, RN, CNRN (Program Director, Parkinson's Disease and Movement Disorders Center, Boston Medical Center, Boston University)

Parkinson's Disease Researcher
- Committee Co-Chair: **Brett Miller,** PT (Owner and Founder of 110 Fitness)

Neurologist (General)
- **Dr. Samuel Frank**, Associate Professor of Neurology, Harvard Medical School, Beth Israel Deaconess Medical Center

Neurologist (Primary Care Provider)
- **Dr. Terrell Y Johnson**, Assistant Professor of Medicine, Boston University Medical School

Health Informaticist
- **Dr. Glenn Tucker**, Chief Medical Officer, Vice President of Medical Affairs, Greater New Bedford Community Health Center

Neurologist (Movement Disorder Specialist)
- **Dr. Anindita Deb**, Associate Professor of Neurology and Neurosurgery, University of Massachusetts Chan Medical School, Co-Chief, Division of Movement Disorders

Diagnosed with Parkinson's Disease
- **James K Cornell**, Managing Partner, Fiduciary Wealth Partners

---

[1] Section 45, p 364 of House No. 4002 codified as Massachusetts G.L. c. 111, s 243

[2] https://www.mass.gov/orgs/parkinsons-disease-registry-and-advisory-committee

Diagnosed with Parkinson's Disease
- ***Matt Keswick***, Keswick Consulting

MDPH Commissioner Appointee
- ***Lauren Fogarty***, Epidemiologist, Bureau of Environmental Health, Massachusetts Department of Public Health

Population Health Researcher familiar with registries
- Unfilled

Population Health Researcher familiar with registries
- Unfilled

Background

Population-based data registries have long been recognized as a way to estimate the incidence and prevalence of non-communicable chronic diseases. The term registry[3] is defined both as the act of recording or registering and as the record or entry itself. Therefore, "registries" can refer to both the programs that collect and store the data and the records that are so created. The term "patient registry" is generally used to distinguish registries that focus on specific health information from other data sets on a specific health disease or diagnosis. The National Committee on Vital and Health Statistics[4] describes registries used for a broad range of purposes in public health and medicine as "an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have a particular disease, a condition that predisposes them to the occurrence of a health-related event, or prior exposure to substances or circumstances known or suspected to cause adverse health effects." Other terms used to refer to patient registries include clinical registries, clinical data registries, disease registries, and outcome registries.

Registries are a mainstay in healthcare. Independent of setting, specialty, or situation, they provide a unique view into what happens, why it happens, and how to improve. Registries empower clinicians, researchers, innovators, and patients to make data-informed decisions to improve. The role of clinical data registries has never been more significant.

This committee has focused on recommendations for establishing a *population-based patient registry* in Massachusetts to determine the incidence and prevalence of Parkinson's disease in the Commonwealth.

The actual incidence and prevalence of Parkinson's disease is not known from current data collection efforts. Researchers have extrapolated from epidemiology studies to estimate that the prevalence of Parkinson's disease in the US in 2017 to be approximately 1,037,000 and would expand to nearly 1,211,128 in 2022[5]. Parkinson's disease is the fastest-growing

---

[3] Webster's English Dictionary. [August 12, 2012]. http://www.m-w.com.

[4] National Committee on Vital and Health Statistics. Frequently Asked Questions About Medical and Public Health Registries. [August 14, 2012]. http://ncvhs.hhs.gov/9701138b.htm.

[5] Marras, C.,et al, Prevalence of Parkinson's Disease across North America. *Nature Partner Journals Parkinson's Disease* (2018) 4:212;doi:10.1038/s41531-018-0058-0

neurological disease in the world. The economic burden of Parkinson's disease in the US has been estimated to be nearly $59.84 billion in 2017 and will rise to nearly $79 billion by 2037.[6] The Michael J Fox Foundation estimates the Massachusetts prevalence rate to be approximately 21,635 (3.14 per 1,000) and the estimated direct and indirect costs to care for Parkinson's disease patients in Massachusetts to be approximately $1.14 billion annually.

It is clearly important to know and understand the incidence and prevalence of this disease. A population-based patient registry is necessary to generate the basic data that will help public health, researchers, medical providers, advocates, and legislators to determine the causes of this disease, evaluate the efficacy of treatments, and uncover inequities in Parkinson's disease healthcare across the Commonwealth. Recognizing that Parkinson's disease has been primarily a disease of older residents, it is also easy to conclude that as this population ages, so will the burden on our society.

Committee Charge

The statutory language in Massachusetts general law, chapter 111, section 34 (Appendix A) charges the committee to advise and assist MDPH in the development and implementation of a Parkinson's disease registry within the Department of Public Health. Section 140 of the FY 2022 enacted budget states that "The department of public health shall begin collecting information for the Parkinson's disease registry established by section 243 of chapter 111 of the General Laws necessary to determine the incidence and prevalence of Parkinson's disease in the commonwealth no later than July 1, 2022."

The statutory charge to the committee is as follows;
  i.   What data shall be collected, including, but not limited to, demographic information and data by areas and regions of the Commonwealth, with specific data from urban, low- and median-income communities and minority communities of the Commonwealth
  ii.   The means of collecting and disseminating such data
  iii. How to ensure privacy and confidentiality of such data
  iv.   The purpose, design, and functionality of the registry
  v.   The implementation of the registry

"The committee will also make recommendations to the department on any information deemed necessary and appropriate for the statistical identification and planning for treatment and education of healthcare providers and persons diagnosed with Parkinson's disease. "

---

[6] Yang, W.,Hamilton,JL, et al. Current and projected future economic burden of Parkinson's disease in the US. NPJ Parkinson's Disease, 6,15 (2020) https://doi.org/10.1038/s41531-020-0117-1

Executive Summary

The Parkinson's Disease Registry Advisory Committee was established in the fall of 2021 to provide recommendations to the Massachusetts Department of Public Health (MDPH) for developing and implementing a Parkinson's disease registry. The sole objective of this committee was to make recommendations to MDPH for establishing a statewide system for the collection of Parkinson's disease data to ultimately estimate the incidence and prevalence of Parkinson's disease in the Commonwealth. The method for which the committee recommends collecting this data is through automated electronic means. The committee recommends the development of an implementation guide *prior* to any data collection. The implementation guide should include ways to analyze the data for quality and completeness as well as to ensure the deduplication of data elements. The committee recommends minimizing any additional burdens on providers to collect the mandated data elements. There should be a reporting mechanism to allow for transparency and validation of data collected. There should be a clearly defined application for access to data. The details for this application process were not discussed by the committee, however, the committee agrees that the MDPH's Internal Review Board (IRB) should be involved in any data accessibility requests for research purposes.

The committee identified two primary barriers to the development and implementation of a Parkinson's Disease Registry in Massachusetts as;

- FUNDING
  Currently, there is no funding allocated to this project. The committee acknowledges that funding is a critical first step. Although it was difficult to estimate a cost for this project. The committee recognized that the MDPH most likely would need an initial funding amount that is higher than ongoing maintenance. The initial funding would be used to develop and build a data collection system, test the system and develop protocols. The ongoing maintenance funding would support day-to-day operations after the initial build is complete.
- MANDATORY REPORTING REQUIREMENTS
  Currently, there is no statute or regulation to require reporting for this registry. The committee recommends a mandatory reporting requirement to ensure the completeness and accuracy of data collected. Without mandatory reporting and consequences for failure to report, it will be difficult to report accurate estimates of Parkinson's disease incidence and prevalence in Massachusetts. The committee proposes similar language as used to collect data for the Massachusetts Cancer Registry. (Appendix F)

Due to the limitations of time, this committee was unable to finalize in-depth recommendations in the following areas:

- Accurate funding estimates
- Defining the specific minimum data elements
- Defining a detailed implementation guide and data reporting guide for MDPH, that includes the specific timelines for reporting
- Eliciting information from potential stakeholders

- Defining the information deemed necessary and appropriate for the statistical identification and planning for treatment and education of healthcare providers and persons diagnosed with Parkinson's disease

Another limitation of the committee was the lack of input from a population health researcher with registry experience. The committee did its best to elicit information from other state registries, however, without a committee member with this expertise, the committee acknowledges that there was a gap in expertise in these areas.

Purpose, Design and Functionality of the Registry

The purpose of the Parkinson's disease registry is to develop a database of accurate historical and current information for research, medical, and public health purposes. The collection of patient data is critical for estimating the incidence and prevalence of Parkinson's disease in the Commonwealth. This database can also inform about possible risk factors, causes, efficacy of treatments, equity of care, and equity of resources. Consequentially, it could strengthen collaborations with stakeholders, increase awareness about Parkinson's disease and other movement disorders, and encourage researchers to investigate the causes, care and treatment of Parkinson's disease in Massachusetts. The Parkinson's disease registry should focus on a commitment to collecting high-quality data for the purposes of population health, public health and medical improvement science. This committee also sees this registry as a tool to assess and ensure equitable care and resources for Parkinson's disease patients across the Commonwealth.

Although registry goals and purposes may vary, this committee feels that if designed with the right approach and built with the right technology, Massachusetts can be a leader in the development and design of a state-wide population-based patient registry for Parkinson's disease.

In committee discussions about purpose and functionality, it became clear that the fundamental approach to designing the infrastructure for gathering data on Parkinson's disease was to take advantage of the progress in healthcare technology, more specifically, the electronic medical record (EMR). The creation of this database should involve a more in-depth review of current data collection and EMR systems utilized by Massachusetts healthcare institutions. This Parkinson's disease registry should predominantly rely on the transfer of data by electronic means whenever and however possible using industry standards. (Appendix B) The burden of this data collection needs to be easy and reliable for reporting entities, all while taking into consideration the need to minimize the impact on clinicians during the data collection and reporting process.

To accomplish this, the committee recommends that the MDPH hold a stakeholder meeting to elicit collaboration and cooperation from data reporting entities across the Commonwealth. Identifying the barriers and solutions to an automated electronic submission of data will allow the MDPH to develop a process utilizing industry standards to transfer the minimum data elements for the Parkinson's disease registry with effectiveness and efficiency. Further detail on

the reporting requirements and guidelines for reporting should be defined in a comprehensive implementation guide. The committee recommends the development of a comprehensive implementation guide prior to any data collection. This implementation guide should provide the design and details for an automated, systematic, electronic transfer of data elements from reporting entities. The committee would recommend a standard timeline for the reporting of information to ensure a uniform, consistent, and complete collection of minimum data elements.

The Parkinson's disease registry should function as a tool to;
- Assist healthcare providers and researchers to better understand expected outcomes, make evidence-based decisions, and share best practices
- Allow patients to gain a greater understanding of Parkinson's disease care that leads to informed decision-making
- Support researchers to make data-driven decisions about clinical trials and surveillance studies
- Assist public health in using data to inform decisions about ensuring health and racial equity of Parkinson's disease care and resources across the Commonwealth

Ensuring Privacy and Confidentiality

Everyone has a role to play in the privacy and security of healthcare data. The MDPH has extensive experience collecting, storing and reporting data all while adhering to state and federal privacy and confidentiality laws and regulations. The development of an implementation guide will assist data reporting entities to adhere to and integrate state and federal health information privacy and security requirements into their processes for submitting data for the Parkinson's disease. The US Department of Health and Human Services (HHS) via the Office of the National Coordinator for Health Information Technology (ONC) the Centers for Medicare and Medicaid Services (CMS) and the Office of Civil Rights (OCR) supports privacy and security through various activities, including enforcement of laws and regulations.

Implementation of a Population-Based Parkinson's disease registry in Massachusetts

Development of a comprehensive implementation guide (Appendix C) will allow for the secure transport of data in the desired format and structure. The guide should also clearly define the minimum data elements (Appendix D) to be collected as well as a data dictionary and glossary of terms and codes used in the Parkinson's disease registry.

Challenges

In the design of a registry and its supporting systems, there are several challenges worth further discussion;
1. While symptoms are generally categorized as one of the determining factors in a Parkinson's disease diagnosis, the conclusory diagnosis can be somewhat subjective. There is a general lack of standards for making a Parkinson's disease diagnosis and for

the reporting of diagnosis, treatment and demographic factors relevant to care and research. This can be a serious challenge for finalizing the design of a Parkinson's disease. There is a limited number of state-wide population-based patient registries for Parkinson's disease, therefore, there has not been a national consensus on the full range of data elements that should be collected. As part of the 21st Century Cures Act, Congress authorized The Centers for Disease Control and Prevention (CDC) in 2016 to develop The National Neurological Conditions Surveillance System (NNCSS). CDC is currently in the process of evaluating a variety of data sources and analytic methods to create an efficient approach for collecting and synthesizing surveillance data that they will utilize. The goal of NNCSS is to increase the understanding of neurological disorders and facilitate research. In the preliminary phase of this project, CDC is focusing on the neurological diseases of Multiple Sclerosis (MS) and Parkinson's Disease (PD). Although this work may help determine the minimum data elements for a Parkinson's disease registry in Massachusetts, the NNCSS is simply meant as a national surveillance tool that will rely on the input of databases like the one that Massachusetts is developing.

2. There is a natural reluctance of physicians to become data collectors. Their training, workload, employer responsibilities, and inclinations are usually aimed primarily toward patient care rather than reporting. The Parkinson's disease registry design and implementation must consider this as a possible challenge when designing the system of data collection methods.

3. The third but probably the most significant challenge as reported by the California Parkinson's Disease Registry (CAPDR), was the de-duplication of data. Multiple sources could be reporting overlapping information on the same patient. The diversity of inputs from disparate sources of data on the same patient requires a clear methodology for resolving duplications.

There were multiple key elements that should be addressed in the design and implementation of a population-based patient registry as relayed by the CAPDR. The California effort may provide valuable lessons learned with regard to how these elements are handled and considered to make a registry successful.

Establishing Authority

For a population-based patient registry at a government level to be successful, mandatory reporting is essential to the long-term sustainability of the registry. The committee recognized that it will be critical to have some kind of legislative action or statutory requirement for reporting. Without such a reporting requirement and some kind of penalty for non-compliance, it will be difficult to ensure a registry that truly reflects the prevalence and incidence of Parkinson's disease in Massachusetts.

Creating Reporting Standards

If armed with the authority to do so, MDPH could develop the minimum data elements and the mandated reporters of data who must comply. It is imperative to have an implementation

guide that lists the set of minimum data elements, the data standards, data formats, and reporting timeframes to ensure quality, comprehensive, and de-duplicated information for the registry. A fundamental decision will be defining the content and source of diagnosis. The decision must take into account the availability of diagnostic data in existing systems. California decided to utilize a billing code rather than a more perfect diagnostic expression for this very reason. California also determined that records would be selected based on case definitions from ICD-10 for G20 Parkinson's disease/Parkinsonism and G90.3 Parkinsonism with neurogenic orthostatic hypotensions for their Parkinson's disease registry[7]. [8]

One of the more important lessons learned, as expressed to the committee during discussions with the CAPDR Director, was the importance of providing input and support from stakeholders in defining the data collection processes. California recommended that Massachusetts create an advisory of data providers, data aggregators, researchers, and public health officials to inform the design and implementation of a Parkinson's disease registry in Massachusetts. The committee recommends forming a sub-committee to define the specific data specifications for electronic transfer to the registry. This sub-committee could help the MDPH in the development of an implementation guide.

Creating a Report Mechanism

Another recommendation of the CAPDR was to consider a reporting mechanism in the design. It will be important to provide transparent and informative Parkinson's disease information about the registry throughout the process. CA created a "*CAPDR Guide to Reporting*"[9] which includes those who are required to report to the registry, what defines a reportable case, the methods for reporting case information to the registry, and the deadlines for data submissions. This guide was developed in collaboration with healthcare providers who have been mandated to report to the CAPDR. California has shared many resources for reference. The committee recommends a sub-committee to help MDPH develop a similar reporting guide.[10] This guide would be important for patients and providers. It would foster transparency about what data is collected, why it is collected and how it will be used.

Data Quality

There must be systems in place to ensure data completeness and data quality. Ensuring that all health care providers are reporting to the registry could be a significant challenge. The committee has recognized that completeness of data may not include data for persons in the military and members of tribes or territories. Efforts should be made to collaborate with both of these groups to ensure accurate prevalence and incidence data for a statewide Parkinson's disease registry.

---

[7] WHO (2016) International Statistical Classification of Diseases and Related Health Problems. 10th Revision, 5th Edition, 2016.
[8] Jankovic J (2008) Parkinson's disease: clinical features and diagnosis. Journal of Neurology, Neurosurgery, and Psychiatry 79 (4) 368-76. Doi:10.1136/jnnp.2007.131045
[9],[11] https://hie.cdph.ca.gov/parkinson-disease-registry.html

Data quality and accuracy should be of paramount importance, however, there needs to be recognition that certain patient data such as the date of Parkinson's disease diagnosis, may be difficult to determine and may not be recorded in an EMR. Additionally, if the diagnosis date is unknown, submitters may substitute the patient encounter data for an unknown diagnosis date, which could lead to unreliable estimates of incidence. Data quality reports should be an important part of the process of ensuring a quality Parkinson's disease registry is implemented in Massachusetts.

The committee recommends that there be a defined set of validation reports to confirm data accuracy. This should be included in the implementation guide. The committee also recommends designing a linkage process for linking with vital records. Obtaining access to death records could be an important part of maintaining accurate records in the Parkinson's disease registry.

Opportunities

The full potential of a Parkinson's disease registry in Massachusetts will be determined by the completeness of data collection and the extent of reliable and accurate information that is consequently made available for research and public health policies. The opportunity to accurately estimate the incidence and prevalence of Parkinson's disease by demographics and geography will allow policy makers, researchers and patients to better understand the causes, treatment efficacy, and inequities that may exist. This information can strengthen stakeholder collaborations and shared resources, improve policies, increase awareness and support, encourage research that will lead to improved care, find effective treatments, and improve outcomes for Parkinson's disease patients in Massachusetts.

Once fully implemented, the committee sees an opportunity to expand data collection to include other neurological disorders. The committee would like to recommend that the development of this Parkinson's disease registry, be structured to allow for such expansions in the future. The design and format of data collection should allow for the expansion of other elements as well. It is hard to envision the new and innovative thinking that may impact the prognosis and progression of this disease. We need to be cognoscente of potential new elements that could influence the prevention, treatment and mitigation of Parkinson's disease and be prepared to review and add data elements at some point in time.

Recommendations of the Committee

The committee recommends a phased approach to the development and implementation of a Parkinson's disease registry in Massachusetts. These recommendations are based on appropriate funding and a legislative mandate to require the collection of specific data elements.

PHASE 1
- Hire appropriate staff for the program
- Develop a list of stakeholders (internal and external). The stakeholder list should include but not limited to medical, public health, data management, epidemiology, and research. Stakeholder discussions should also include VA and Indian Health Services
- Meet with stakeholders to understand the challenges and barriers to electronic transfer of data as defined by the committee
- Develop a webpage structure for keeping the public informed

PHASE 2
- Develop a comprehensive implementation guide (table of content in Appendix C)
- Develop reporting guide that defines the onboarding process for entities required to report
- Develop a communication plan for providers, researchers and patients
- Conduct a pilot for the transmission of electronic data. Ensure data quality and completeness in the pilot

PHASE 3
- Begin the collection of data
- Develop a data quality plan
- Develop a de-duplication plan
- Conduct data quality checks according to the plan

PHASE 4
- Develop a plan for internal and external use of data
- Develop a patient portal. The portal should include a questionnaire to offer additional information to the patient's record in the registry as well as, give the patient an opportunity to offer edits/updates to their information in the registry database
- Develop a plan for data access and release of data for research and epidemiologic studies. Policies and procedures for using Parkinson's disease registry data should follow similar MDPH protocols for acquiring data from other registries and data sets. Researchers would apply for access to data using Section 24A authorizing the commissioner of public health to approve "scientific studies and research which have for the purpose the reduction of morbidity and mortality with the Commonwealth. If possible, it is recommended that the regulations be updated to include the Parkinson's disease registry.
- Develop an interface with vital records to ensure that the registry is an active database of "living" cases, linkages with death records will be needed at various intervals to ensure accurate prevalence estimates.
- The committee recognizes that new disease specific information and new technologies will evolve over time, and therefore, recommends regular review of the data fields and collection processes with modifications as needed.

Acknowledgments

The committee would like to thank and acknowledge the efforts of all committee members who contributed their time and expertise to this important project.

The committee would like to give special thanks to the California Department of Public Health for sharing their knowledge and lessons learned related to the development of a Parkinson's Disease Registry in California. A special thanks to Dr. Mark Damesyn for his candid and thoughtful presentation to the committee.

The committee would also like to that the Michael J Fox Foundation for sharing their knowledge and experiences working with other states as they develop similar registries. A special thanks to Ted Thompson and Julia Worcester for their time and expertise.

Massachusetts General Law

SECTION 45. Said chapter 111 is hereby further amended by adding the following 670 section:- 671 Section 243. (a) The department shall establish a Parkinson's disease registry for the collection of information necessary to determine the incidence and prevalence of Parkinson's disease in the commonwealth. (b) There shall be within the department a Parkinson's disease registry advisory committee to advise and assist in the development, implementation and progress of the Parkinson's disease registry established in subsection (a). The committee shall review and submit recommendations on: (i) what data shall be collected, including, but not limited to, demographic information and data by areas and regions of the commonwealth, with specific data from urban, low and median income communities and minority communities of the commonwealth; (ii) the means of collecting and disseminating such data; (iii) how to ensure privacy and confidentiality of such data; (iv) the purpose, design and functionality of the registry; and (v) the implementation of the registry. The committee shall recommend to the department any information deemed necessary and appropriate for the statistical identification and planning for treatment and education of health care providers and persons diagnosed with Parkinson's disease. The committee shall consist of the commissioner, or a designee, and 10 members to be appointed by the commissioner as follows: 3 physicians, 1 of whom shall be a general neurologist, 1 of whom shall be a movement disorder specialist and 1 of whom shall be a primary care physician; 1 health informaticist; 2 population health researchers familiar with registries; 2 Parkinson's disease researchers; and 2 persons diagnosed with Parkinson's disease. The committee shall meet at least bi-annually to assess registry progress and recommend changes.

Language in FY2022 Enacted budget

"The department of public health shall begin collecting information for the Parkinson's disease registry established by section 243 of chapter 111 of the General Laws necessary to determine the incidence and prevalence of Parkinson's disease in the commonwealth no later than July 1, 2022."

Appendix B

Data Standards in Healthcare

The table below details the data standards for the electronic transfer of information in healthcare. Overarching all the data standards below is the security of data. All transfers utilize the Security Standards defined in HIPAA (Health Insurance Portability and Accountability Act of 1996).

Data Transport Standards

FHIR	API patient data exchange
Direct	Secure message exchange
DICOM	Medical image exchange
SCRIPT	e-prescription exchange
EDISC	Clinical trial data exchange

Data Content Standards

C-CDA	Clinical documents
HL7 v2&v3	Clinical messages
USCDI	Set of exchangeable data elements

Terminology Data Standards

ICD-10 CM	Diagnosis and Disease codes
CPT	Outpatient services and procedures
HCPCS	Medical equipment and supplies
CDT	Dental services
SNOMED CT	Clinical concepts
LOINC	Laboratory observations
NDC	Pharmacy products
RxNorm	Clinical drugs

Appendix C

Suggested Table of Contents for Implementation Guide

1. Introduction
2. Purpose
3. Massachusetts Parkinson's disease registry reporting requirements
    a. Who is required to report?
    b. Parkinson's Disease Case definition
    c. Criteria for reporting?
    d. How to Report: Report Methods and Reportable Data fields
    e. Schedule of reporting
4. Technical Implementation
    a. Methods for Reporting
        i. Automated Data Entry
        ii. Manual Data Entry
    b. Minimum Data Elements
    c. Transmission Methods
    d. Onboarding Process
        i. Registration of Reporting Entities
        ii. Data Submission testing and validation
5. Ongoing Data Quality and Validation

Appendix D
Data Requirement Recommendations

Data Content Area	Required	Field Name
Facility	R	Reporting Facility Name
	R	Reporting Facility ID
	R	Facility Address
	R	Facility Phone Number
	R	Date and Time of Data Transfer
	R	Facility Type
Patient Demographics	R	Name (Last, First, Middle
	R	Date of Birth
	R	Sex (gender)
	R	Race
	R	Ethnicity
	R	Patient address, street incl. # (current)
	R	Patient address, city (current)
	R	Patient address, state (current)
	R	Patient address, zip (current)
	R	SSN (at least the last 4 digits)
	R	Medical Record Number
Patient Information	R	Date of PARKINSON'S DISEASE symptom onset
	R	Date of Diagnosis of PARKINSON'S DISEASE
	R	Was PARKINSON'S DISEASE DX Confirmed by Neurologist (Y/N)
	R	Age at onset (symptoms or Dx)
	R	Does Patient have 1st degree relative with PARKINSON'S DISEASE (Y/N)
	R	Is there presence of moderate to vigorous exercise of 150 min/wk (Y/N)
	R	Is there presence of dementia or mild cognitive impairment (Y/N)

Other data elements were discussed as important and would be helpful however they may be difficult to collect through electronic transfer. These data elements include:
Medications (past and present), Medical history, and Parkinson's disease diagnostic test results such as DaTSCAN, Skin Biopsy, and UK Brain Criteria diagnosis.

Funding requirements

1. IT Development: Funds to design and implement a data collection system to transfer data using industry standards, maintain the data securely, and store the data. The system must be able to generate analytics and reports for the purpose of ensuring data integrity, quality and completeness. Without the specific technical requirements (beyond the scope of this committee) it was difficult for the committee to obtain an accurate estimate for the cost for this work.

2. Program management: The staffing needed for this project was also difficult to estimate. The committee recognizes that the MDPH may be able to utilize current staff and resources for some of the activities, the committee did not have the time or resources to fully access the MDPH resources that may be available. The committee identified skill sets that would be required to develop and build this program. The following skill sets were compiled from reviewing other registry information, discussions with other Parkinson's disease registries, and discussions among committee members. The committee recommends a project manager who has some understanding of registries. This person would oversee the day-to-day operations of the registry. There should also be someone who has a strong understanding of healthcare data collection, storage and maintenance. There should also be a person with medical background with an understanding of Parkinson's disease, to communicate with healthcare providers, advocacy groups and other stakeholders. This person should also have some quality improvement experience. Another skillset that would support this program would be an administrative person. Someone to help manage the logistics and scheduling of the program activities.

Due to the committee's difficulty to estimate funding, we thought it would be helpful to present the funding of other registries in Massachusetts.

The Massachusetts ALS Registry is funded solely with state funds. The funding for FY2021 was $287,000. The registry is almost completely manual with no mechanism to collect data through electronic means using healthcare data standards. This registry was developed and implemented prior to the universal use of electronic medical records and electronic data transfers.

The Massachusetts Cancer Registry receives funding from several state and federal sources. The cancer registry collects most of its data through electronic means and years of experience to support its work. The cancer registry FY2021 funding was $6,533,381.

The committee estimates that the costs for developing and implementing a Parkinson's disease registry in Massachusetts would be somewhere between these two. This cost estimate is based on the committee's understanding of the estimated number of people in Massachusetts diagnosed with Parkinson's disease and the costs associated with collecting data electronically.

Suggested legislative language for mandatory reporting
The proposed language is modeled from the legislative language requiring data reporting for the cancer registry. (m.g.l. ch. 111, sec. 111B)

"The department shall, subject to appropriation, establish a registry to record cases of Parkinson's Disease that occurs in residents of the commonwealth, and such information concerning these cases as it shall deem necessary and appropriate in order to conduct epidemiologic surveys to apply appropriate preventative and control measures.

The commissioner shall require the reporting of cases of Parkinson's disease and the submission of such specific additional information on reported cases or control populations as is deemed necessary and appropriate for the recognition, prevention, and control of such disease.

The department shall, subject to appropriation, maintain comprehensive records of all reports submitted pursuant to this section. Such reports shall be confidential in accordance with section seventy and shall be released by the department only upon written request of the patient, guardian, executor, attorney, or other person designated in writing by said patient. Such reports, records, or information contained therein, may also be released by the department to persons authorized by the commissioner to conduct research studies or to other persons, but no such studies shall identify the subjects of said reports or records.

Nothing in this section shall be construed to compel any individual to submit to medical or department examination or supervision.

The department shall make such rules and regulations as necessary to implement the provisions of this section pursuant to chapter…"

Massachusetts Resources for Parkinson's Disease

Massachusetts is home to a number of resources providing care and support to individuals living with Parkinson's disease. Resources also exist for those who provide care, including both family caregivers and health and wellness professionals.

Health Care Delivery

Movement Disorder Specialists

There are approximately 40 movement disorder specialists (MDS) here in Massachusetts. These neurologists have received fellowship training in movement disorders. The majority of specialists provide care in Eastern and Central, Massachusetts and receive referrals from throughout New England and beyond. Many MDS practices are in large academic medical centers, conduct research and train future neurologists and MDS fellows. Comprehensive Parkinson Centers are located at Beth Israel Deaconess Medical Center (BIDMC), Boston University Medical Center (BUMC), Brigham and Women's Hospital (BWH), Massachusetts General Hospital (MGH), Lahey Hospital, St. Elizabeth's Hospital, and the University of Massachusetts Memorial Hospital. These centers may include surgical programs, interdisciplinary and palliative care programs. During the past decade, there has been an increase in the number of MDS located in non-academic practices throughout the state. It is important to recognize even with this number of specialists accessing new patient appointments can take several months.

Rehabilitation Specialists

Rehabilitation Specialists including Physical Therapists, Speech and Language Pathologists and Occupational Therapists provide essential care to PD patients across the course of care. Here in Massachusetts, there are several experienced therapists affiliated with Parkinson Centers and Rehabilitation Hospitals. Comprehensive Parkinson programs exist in Rehabilitation Hospitals such as Spaulding and Encompass. Boston University Sargent College Center for Neurorehabilitation provides comprehensive clinical care, research, education, and consultation to health providers and the patient community. The American Parkinson's Disease Association National Rehabilitation and Resource Center is located in Boston. Many Massachusetts Rehabilitation Providers have taken advantage of National Training Programs (Lee Silverman Voice Treatment, Speak Out, Parkinson Foundation Team Training to name a few). These programs have increased awareness of the needs of the patient with Parkinson's disease receiving care in the hospital, outpatient setting and in the home.

Psychosocial Providers

Psychosocial support is an important need for patients and care providers. There are Licensed Clinical Social Workers (LICSW) and psychologists who have developed expertise in Parkinson's disease. There are not enough psychosocial providers, and this essential support remains an unmet need.

Advocacy Support

There are many advocacy organizations at the national and local level providing various types of support to the Parkinson Community. Three national organizations provide significant support here in Massachusetts. The American Parkinson Disease Association (APDA) currently funds two Advanced Center of Research Centers at Boston University Medical Center and Brigham and Women's Hospital. APDA has also funded an Information and Referral Center located at BUMC since 1979. Services include a telephone helpline, support group development, and educational and support programming including the "Good Start" and "PRESS" program for newly diagnosed people. A statewide chapter exists which raises funds to support Parkinson's disease programming and offers individual financial assistance. The Michael J Fox Foundation (MJFF) provides support to the Parkinson Community through large and small research programs with a goal to improve time to diagnosis, provide new treatments and ultimately find a cure. The Parkinson Foundation (PF) has established two Centers of Excellence here in Massachusetts, (Beth Israel Deaconess Hospital and Massachusetts General Hospital). Specialized programs exist to educate health care professionals including Safra-Parkinson Foundation training for nursing and physical therapy, as well as the Parkinson Foundation Team Training (formally ATTP). The Parkinson Foundation also provides grants to support research and local health and wellness programs.

These advocacy groups are sensitive to the needs of diverse populations and work very hard to deliver services equitably. They, along with smaller advocacy groups sponsor events that provide education to patients and families.

Health and Wellness

There is an ongoing need to support the physical and mental health needs of individuals living with Parkinson's disease. A number of well-designed and thoughtful programs exist across the state. Some examples include Jewish Family and Children's Services Parkinson Family Support Program, 110 Fitness, located on the South Shore, and Parkinson Fitness on the North Shore. Exercise and Wellness programs exist in several YMCA's, Jewish Community Centers, and Senior Centers. Signature Parkinson programming includes boxing, high Intensity workouts, and choral programs exist in many communities. There are approximately thirty Parkinson's disease support groups facilitated by health professionals or peer leaders in Massachusetts. Some of these groups support members of a community while others support specific populations, (i.e., young onset of Parkinson's disease). Support Groups are currently delivered both virtually and in-person. Virtual programming has improved access to those who cannot attend a meeting in person.

Veteran Programs

There are two Parkinson Consortium Centers in Massachusetts for Veterans who enroll in the Veteran's Administration healthcare system (VA). Consortium Centers are regional Parkinson's disease specialty clinics. The Consortium Centers are located in the VA Boston Health Care system, Jamaica Plain Campus and in the VA Central Western Massachusetts,

Northampton, Massachusetts. The closest VA Parkinson's Disease Research, Education and Clinical Center (PDRECC) is located at the VA Center of Excellence is in Philadelphia.

Biotechnology/Industry

Massachusetts is home to several biotechnology and pharmaceutical companies developing therapies for Parkinson's disease. This resource provides tremendous support for researchers and the community at large.