February 11, 2023

Consensus-Based Recommendations for Establishing Statewide Parkinson's Disease Registries

Proceedings of the Parkinson's Disease Registries Data Summit

THE MICHAEL J. FOX FOUNDATION

FOR PARKINSON'S RESEARCH

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Purpose and Acknowledgment

The purpose of the National Parkinson's Data Summit (the Summit) was to build a consensus among operators of state population-based Parkinson's disease data registries and researchers about the data components that should be included in such registries in accordance with their level of maturity: basic, enhanced and aspirational. While meeting this objective, the participants also addressed challenges and opportunities critical to further the research and practice that enhances the value of such registries. Participants invited to the Summit included:

- representatives of existing and emerging Parkinson's disease registries
- scientists and scholars from selected disciplines who have been engaged in Parkinson's research
- advocacy organizations concerned with Parkinson's disease
- representatives from federal agencies having a mission related to Parkinson's
- research and policy staff members of The Michael J. Fox Foundation for Parkinson's Research.

These proceedings attempt to summarize the robust presentations and discussion at the Summit and to present the beginning of a consensus on the specific data that population-based registries may wish to consider in designing their data collection programs and policies. This document aims to provide a basis for state-level population-based Parkinson's disease registries to (1) create the foundation for registry data collection; (2) make decisions on the basic, enhanced and aspirational data elements that each registry might collect; and (3) institute the policies and practices that will ensure viability and sustainability of such registries. While each state registry must respond to the policies and principles of its individual stakeholders, a basic tenet of the Summit and this document is that the use of common and shared processes and standards leads to more informed decision making about public health policy regarding Parkinson's disease.

The work products of any convening such as this Summit are only as good as the participation of the attendees. The Michael J. Fox Foundation is pleased to have sponsored this Summit as a starting point in this important collaboration across states and within the research community. We acknowledge and appreciate the contributions of all the presenters, discussion leaders and active participants who created what we believe was a robust and meaningful meeting that has produced useful information for managing data collection in population-based Parkinson's disease registries. The list of participants is provided in Appendix A.

Ted Thompson, JD
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THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH

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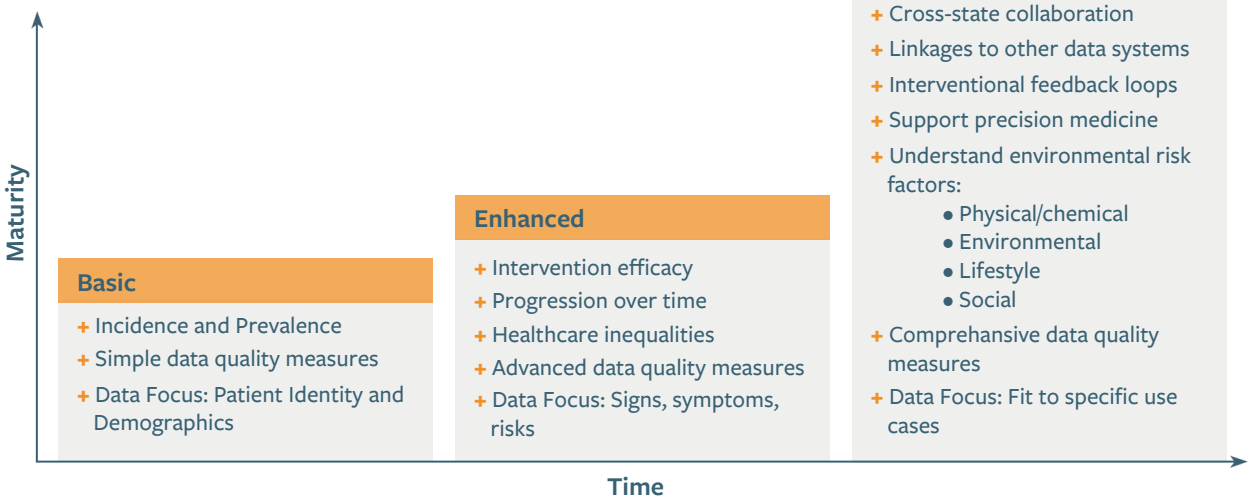
Executive Summary

Public health agencies have long recognized that population-based data registries are required to estimate the incidence and prevalence of non-communicable chronic diseases; however, a fundamental challenge is to determine the scope of the data collection. The purpose of the National Parkinson's Data Summit (the Summit) was to build a consensus between the Parkinson's Disease (PD) research community and operators of state population-based PD registries around a maturity model for registries' data collection.

Summit participants ultimately coalesced around a 3-level maturity model:



Basic

+ Incidence and Prevalence
+ Simple data quality measures
+ Data Focus: Patient Identity and Demographics

Enhanced

+ Intervention efficacy
+ Progression over time
+ Healthcare inequalities
+ Advanced data quality measures
+ Data Focus: Signs, symptoms, risks

Aspirational

+ Cross-state collaboration
+ Linkages to other data systems
+ Interventional feedback loops
+ Support precision medicine
+ Understand environmental risk factors:
  - Physical/chemical
  - Environmental
  - Lifestyle
  - Social
+ Comprehansive data quality measures
+ Data Focus: Fit to specific use cases

Summit attendees also recommend that:

Policymakers

+ Define "Parkinson's disease" broadly for the purpose of automated data collection.
+ Expand the number of state Parkinson's Registries to ensure a broad cross section of the United States population is represented.
+ Enact policies and programs that address the shortage of qualified health care experts necessary for the success of a PD registry.
+ Consider health equity challenges when enacting registry legislation.

Implementing Bodies

+ Create a clear statement of value for your jurisdiction's registry.
+ Reduce data entry burden on data providers, where feasible.
+ Adopt best practice data standards to increase interoperability.
+ Establish a working group of officials from states with enacted registry legislation to increase collaboration and knowledge transfer between jurisdictions.

Stakeholders & Advocates

+ Establish tools and training to improve problem list data entry quality.
+ Develop and publish toolkits to standardize data collection regarding PD signs and symptoms.
+ Establish an advisory council to regularly review diagnosis code lists and advise registries on best practices.
+ Regularly convene a consortium to develop best practices.
+ Continue to act as a convener and work to develop and disseminate educational materials to facilitate the establishment and sustainability of state registries.

Ultimately, the success of registries will be dependent on partnerships, representation of diverse stakeholder voices, and a commitment to collaboration. Ensuring buy-in and clear value-adds for those involved will enable registries to not only support desired research and policy goals, but overcome the challenges pertaining to data quality, collection, privacy, distribution, and utility. Working together at the intrastate, interstate, and national levels can provide ever-increasing value to the research and patient communities.

Introduction

As states continue to establish population-based Parkinson's disease registries to meet legislative mandates to address the burdens of Parkinson's disease, a fundamental challenge is to determine the specific scope and content of the data collection that will be the basis of the registry. The Summit started with the assumption that there is and will be varying levels of maturity in data collection as a function of the extent to which the registry is able to support more than the basic surveillance purposes for which registries are initially established. Maturity levels are categorized as basic, enhanced, and aspirational. Each level is based on the functionality expected as registries grow and expand to serve clinicians, researchers and patients more completely.

Critical to aggregation of state registry data to more accurately determine incidence and prevalence and to service other policy and research goals are (i) a common understanding of the specific data components that should be collected and (ii) a consensus on the meaning and measure of data components. The National Summit sought to begin to create such a consensus.

These proceedings summarize and link the topics discussed in the Summit. Beginning with a summary of the state of Parkinson's disease registry implementation in the U.S., the proceedings continue with (i) preparation required for the creation of a Parkinson's disease registry, (ii) the considerations in creating a registry meeting basic, enhanced or aspirational levels of maturity, and (iii) the issues that must be addressed to create a sustainable registry. The proceedings close with explicit recommendations to stakeholders involved in the creation of a registry.

Acronyms

AMP-PD	Accelerating Medicines Partnership-Parkinson's Disease
CBD	Corticobasal Degeneration
C-CDA	Consolidated Clinical Document Architecture
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CDE	Common Data Elements
CDM	Common Data Model
CDS	Clinical Decision Support
CMS	Center for Medicare and Medicaid Services
CMIO	Chief Medical Informatics Officer
CPDR	California Parkinson's Disease Registry
CPT	Current Procedural Terminology
CSTE	Counsel of State and Territorial Epidemiologist
DRG	Diagnosis Related Group
dQM	Digital Quality Measures
eCQM	Electronic Clinical Quality Measures
eCR	Electronic Case Report
EHR	Electronic Health Record
eICR	Electronic Initial Case Report
eMerge	Electronic Medical Records and Genomics
FDA	Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
GP2	Global Parkinson's Genetic Program
GUID	Global Unique Identifier
HHS	United States Department of Health and Human Services
HIE	Health Information Exchanges
HL7	Health Level-7 standards development organization
H&Y	Hoehn and Yahr Scale
i2b2	Informatics for Integrating Biology and the Bedside
ICD10	International Classification of Diseases
IMO	Intelligent Medical Objects (vendor vocabularies)
LOINC	Logical Observation Identifiers Names and Codes
MJFF	The Michael J. Fox Foundation for Parkinson's Research
MMSE	Mini-Mental State Exam
MoCA	Montreal Cognitive Assessment
MSA	Multiple System Atrophy
NDC	National Drug Codes
NIH	National Institutes of Health
NINDS	National Institute of Neurogenetic Disorders and Stroke
NLM	National Library of Medicine
NNCSS	National Neurologic Conditions Surveillance System (CDC)
NPCR	National Program of Cancer Registries
OHDSI	Observational Health Data Sciences and Informatics

Acronyms

OMOP	Observational Medical Outcomes Partnership (see OHDSI)
ONC	Office of the National Coordinator for Health Information Technology
ORMIS-PD	Ontology-based, Real-time, Machine Learning Informatics System
PCORnet	National Patient-Centered Clinical Research Network
PDGene	PD Generation study
PDQ39	Parkinson's Disease Questionnaire about difficulties across dimensions of daily living
PEG	Parkinson Environment Gene study (UCLA)
PPMI	Parkinson's Progression Markers Initiative
PSP	Progressive Supranuclear Palsy
QHIN	Qualified Health Information Network
RCE	Remote Code Execution
RxNorm	Normalized Names and Codes for Clinical Drugs
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms
SDOH	Social Determinants of Health
TEFCA	Trusted Exchange Framework Common Agreement
UCE-PD	UCLA-California PD Registry
UPDRS	Unified Parkinson's Disease Rating Scale
USCDI	United States Core Data for Interoperability (USCDI)
USCDI+	Announced September 2022 (www.healthit.gov/topic/interoperability/uscdi-plus)
VSAC	Value Set Authority Center (NLM)
WG	Working Group

Why Registries?

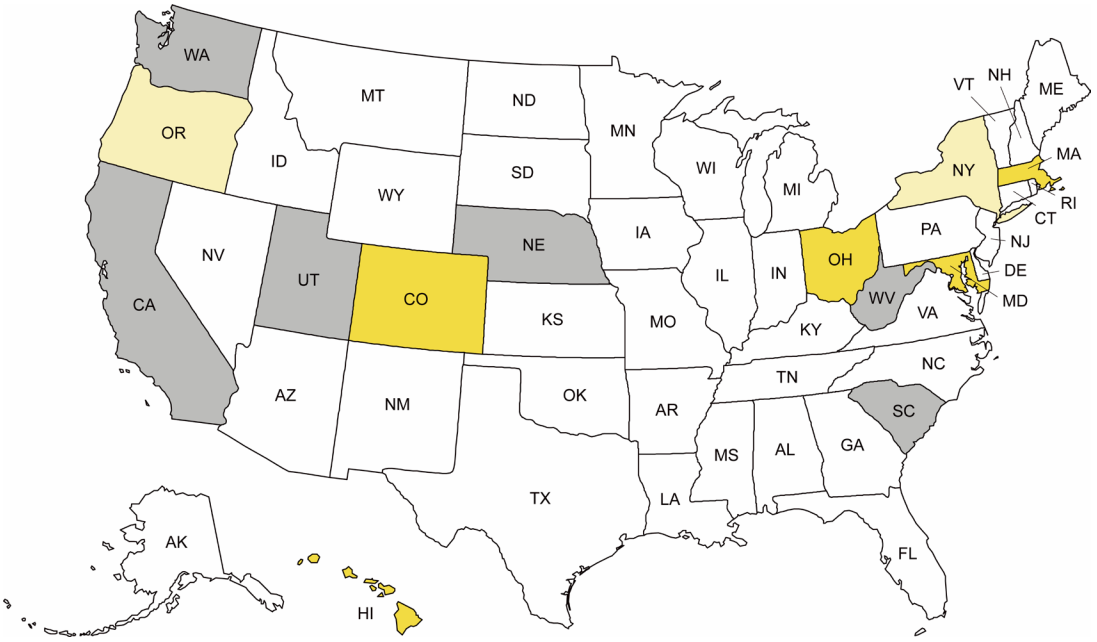
Public health agencies have long recognized that population-based data registries are required to estimate the incidence and prevalence of non-communicable chronic diseases. Registries have been developed throughout the world for the purpose of surveillance of these diseases to inform public health agencies and the public on the extent of the disease and to identify trends amidst population centers to support the development of public health interventions. The more common registries are focused on those diseases with the highest mortality rates, such as cancer, but many registries have been built for other diseases such as amyotrophic lateral sclerosis (ALS). In the U.S., federal and state statutes call for the creation of cancer data registries in many states. States are beginning to also develop registries for Parkinson's disease (PD).

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 PD in the U.S. was 1,037,000 in 2017 and would expand to nearly 1,211,128 by 2022 (Marras et al., 2018). Recently, a published study indicated that the incidence of Parkinson's is 50% higher than previous estimates; 90,000 Americans each year are being diagnosed with the disease. The economic burden of PD in the United States has been estimated to be nearly $52 billion in 2022 and rising to $79 billion by 2037 (Yang et al., 2020).

A population-based registry is necessary to generate the basic data that will help researchers, treatment providers and legislators determine the causes of the disease, evaluate the efficacy of treatment, uncover inequities in PD healthcare, and make decisions about the allocation of resources for prevention and treatment. Just as registries can enable us to better understand the full, diverse, and heterogeneous nature of Parkinson's disease in each state, a diversity (if not a plurality) of state registries will scale that effect, ensuring that we are able to capture regional nuances and national trends and to minimize over or underrepresentation.

The Current State of State Registries

An increasing number of states are becoming interested in creating their own Parkinson's disease registries. The status of adoption is illustrated in this diagram:



States with registries

States with registry-related legislation

States with anticipated legislation in 2023

Contributed by Julia Pitcher

Current

+ **California**
Established in 2017
+ **Nebraska**
Established in 1996
+ **Utah**
Established in 2015
+ **Washington**
Voluntary registry exists

2022 Additions

+ **South Carolina & West Virginia** passed legislation to create state registries.

In Progress

+ **Maryland & Massachusetts** established advisory councils to issue reports on what registries could look like, legislation to formally establish registries expected in 2023.
+ **Colorado, Hawaii & Ohio** have had registry bills before their legislatures, additional legislative action expected in 2023.
+ **New York & Oregon** are expected to have registry-related legislation introduced in 2023.

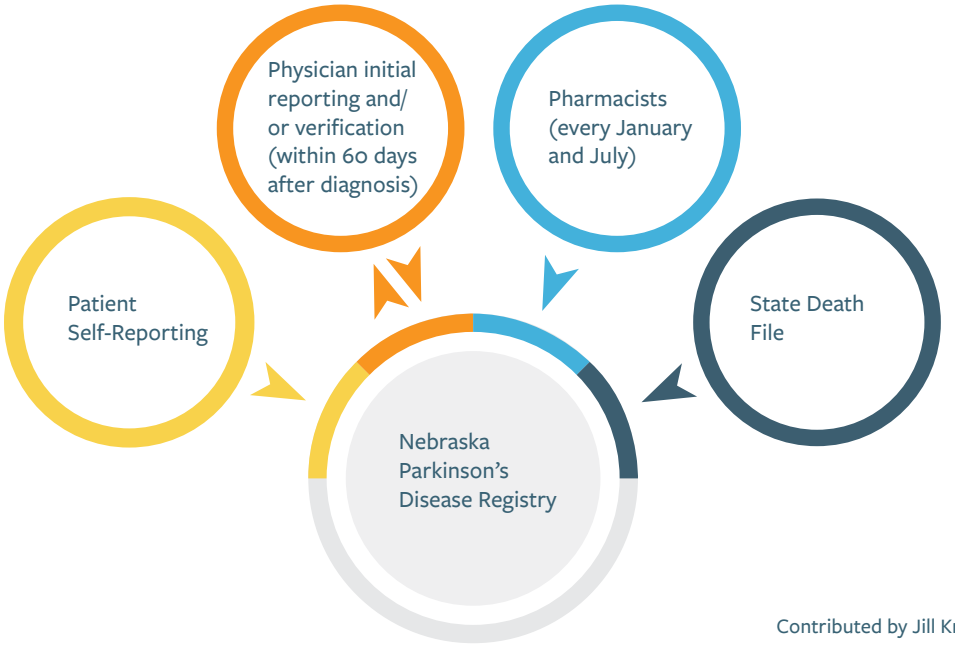
Prior to 2022, there were four known Parkinson's registries in the United States: Nebraska (1996), Washington (2007), Utah (2015), and California (2017). Washington operates a voluntary repository and is partially funded by the American Parkinson's Disease Association – Northwest Chapter. The Utah Registry is also a voluntary repository, within the University of Utah School of Medicine. Neither of these registries produce annual reports nor do they make statistical data available to the public.

In 2022, The Michael J. Fox Foundation (MJFF)'s State Government Relations team led an effort to submit and successfully passed statewide registry legislation in three states: West Virginia, South Carolina, and Maryland. The West Virginia and South Carolina efforts will establish a statewide registry through their medical universities to go live by the end of 2023 and will submit their data to their respective state departments of health. The Maryland legislation established an interim advisory committee that recommended that the state would benefit from a fully landscaped registry and will submit recommendations to that effect in a report due in early 2023. The MJFF State Government Relations team is pursuing similar legislation in several more states during the 2023 legislative sessions. Some states are also considering legislation to establish broader neurodegenerative disease registries, where PD would be one of several included conditions.

To illustrate the variations in state approaches to the creation of a Parkinson's disease registry, the Summit included presentations from Nebraska and California.

Nebraska

Nebraska was the first state to begin collecting data in a Parkinson's disease registry, in 1997. The state took the approach of identifying several diverse sources of data.



Contributed by Jill Krause

In 2017 Nebraska began working on automating the data collection efforts, developing an electronic system that allows manual entry of individual cases, spreadsheets to be uploaded, or data exchange to be set up. In the future Nebraska expects to work through a health information exchange created in the state and linking to provider health information systems. This will include collecting prescription drug monitoring program data to get case reports associated with specified Parkinson's medications. Since legislation has led to changes in data elements required by healthcare providers, system modifications are needed before that data is able to be processed. Currently the system is primarily used by pharmacies to directly enter their data or upload their data files.

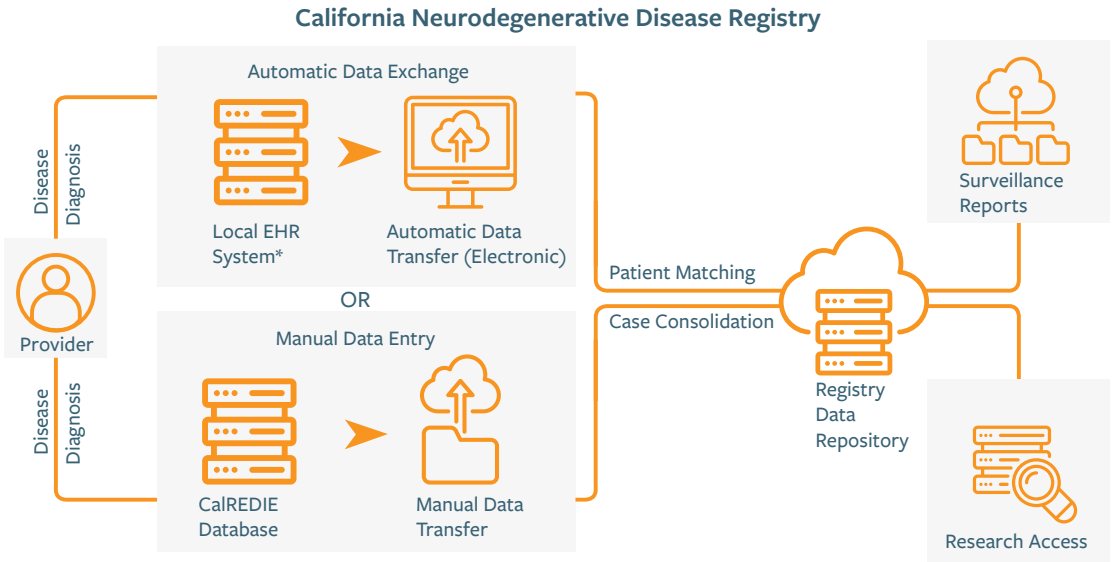
In its modernization and automation of reporting, Nebraska is seeking to build a system that will:

- accept case reports of multiple diagnoses that hold similarities to PD
- link to other state datasets such as its cancer and traumatic brain injury registries and to the state death file
- Include other Public Health conditions, and
- use the HL7 data standard to provide flexibility and detail to be of use on a national level.

Nebraska cited making data providers aware of and responsive to reporting requirements as a challenge to implementation of the registry. Resources are also stretched to accommodate the work required to gather, correlate, deduplicate and make reports from the assembled data.

California

California began the creation of its Parkinson's disease registry in 2017, with legislation that created a pilot project. The initial legislation had an expiration that required renewal for the program to continue, and there was some uncertainty about the sustainability of the registry as the expiration date approached. The legislature ultimately broadened the program to include a neurodegenerative disease scope, as well as removed the sunset date. California's program today consists of two major alternative ways of collecting data.



*Local Electronic Health Records System

Relying on its experience with the California Cancer Registry, the development of the Parkinson's disease registry was predicated on using automated extraction of data from electronic health records systems as the primary means of collecting data. An alternative portal for direct entry was also created for use by clinicians who were not served by electronic health systems. While over 85% of all reported cases came from automated records exchanges, the rates of duplicates was higher from automated sources than from direct entry. California has also found that the manual entry of records results in generally more complete data as some electronic health systems do not contain entries for all of the data elements of interest to the registry.

The results from the collection and curation of Parkinson's case records appear to be consistent with estimates of incidence and prevalence from other sources and confirm the increasing impact as the population ages.

In its initial roll out, the California registry was challenged by the reluctance of physicians to agree with the reporting detail that was originally contemplated as the basic reporting level. After serious objections arose, the response was to limit the initial implementation to a relatively small data set in order to minimize the impact on data providers.

The California Department of Public Health is exploring initiatives to make the registry more useful in a variety of ways, such as being helpful in identifying potential participants in clinical trials.

National Efforts Supporting Data Collection

The Centers for Disease Control and Prevention (CDC) has been tasked by Congress to create the National Neurological Conditions Surveillance System (NNCSS).

National Neurological Conditions Surveillance System (NNCSS) - Project Plan

Stage 1
Learn What Works

Conduct demonstration projects using multiple sclerosis and Parkinson's disease.

+ Assess potential data sources.
+ Select case-identification algorithms.
+ Produce surveillance estimates.
+ Propose approaches for NNCSS build out the extension.

Stage 2
Build Out NNCSS

Implement approaches for ongoing surveillance of multiple sclerosis and Parkinson's disease.

+ Validate findings.
+ Maintain and expand initial surveillance.
+ Refine approach and costs.
+ Explore criteria to prioritize conditions to add to NNCSS.

Stage 3
Extend NNCSS

Implement approaches to initiate surveillance of additional neurological conditions.

+ Produce surveillance estimates for new conditions.
+ Continue surveillance for the initial conditions.
+ Ensure methods and data sources stay state-of-the-art.

Contributed by Shawna Mercer

The CDC also has a leadership role in the development of a national electronic case reporting system (eCR): automated generation and transmission of case reports from the electronic health record (EHR) to public health agencies for review and action. As of January 1, 2022, the Center for Medicare and Medicaid Services (CMS) Promoting Interoperability Programs will require hospitals, critical access hospitals, including and Merit-based Incentive Payment System providers to report to public health agencies for:

+ syndromic surveillance reporting
+ electronic reportable laboratory result reporting
+ electronic case reporting
+ immunization registry reporting

As of July 2022, there are 173 reportable conditions that can be reported using eCR. Parkinson's disease was added in June 2019. The eCR program has led to the development of the electronic initial case report standard (eICR) that specifies data elements related to the initial reporting of a case. The eICR data standards conform to the U.S. Core Data for Interoperability (USCDI) standards.

Gathering Stakeholders

Summit participants agreed that to be successful, state agencies desiring to create a Parkinson's disease registry must form partnerships with the key stakeholders that will be affected by such a program. The key stakeholders are:

- data providers (particularly, but not limited to, neurologists)
- healthcare organizations
- health care IT vendors and informatics organizations
- Researchers, provider professional associations
- Patient organizations and patients
- Government partners (CDC, National Institutes of Health [NIH], CMS, Office of the National Coordinator for Health Information Technology [ONC], Food and Drug Administration [FDA], state chronic disease and aging programs)
- Legislators

Organizers of a Parkinson's disease registry must help audiences see that the value of the registry is worth the effort. Convening stakeholder segments to describe the value premise and discuss implementation concepts can build consensus among the various groups, which is necessary to make the registry successful. Working through membership associations is also a proven approach.

Developing a Shared Vision

Once the stakeholders concur that a Parkinson's disease registry is valuable and that the state has both an interest and an obligation to create it, there remains the important step of developing a shared vision to form the basis for the detailed and mandatory reporting that must eventually emerge in a state statute.

At the policy level, the shared vision must deal with the critical issues that can impede success. In practice, the shared vision should seek a consensus on the cases to be reported, the ways in which data will be collected, the responsibilities of each class of stakeholders including the originators of data, and the ways in which the data will be used.

Registry organizer in other disciplines have found it helpful to create a document that describes the process by which stakeholders can work toward consensus on how to establish and operate registries. Giving each class of stakeholder a voice in the creation of such a process encourages buy-in for the eventual implementation of the Parkinson's disease registry.

Creating a Governance Structure and Process

While government agencies must retain decision-making authority, the creation of a governance process by which the various stakeholder groups have clear input to decision making is a critical element in the long-term survival and stability of the registry. In other areas, CDC has generally recommended that states create advisory committees that can be used to develop and communicate audience-specific value statements, as well as provide recommendations and reviews that enlighten decision-makers and provide transparency to the stakeholder community. Stakeholder groups must have representation in the design and sustainment processes and their feedback to agency management must be given reasonable consideration. Further, these advisory committees should not only be considerate of the specific nuances of their given jurisdiction, but also enable participation in activities pertaining to inter-state transfer of knowledge pertaining to registry establishment and operation.

Defining "Parkinson's Disease" For Registry Purposes

A fundamental decision in the creation of the Parkinson's disease registry is the definition used for counting cases and collecting data. The challenge faced by any registry is that the standard for the diagnosis of Parkinson's disease is complex and no universal recording of the diagnosis that can definitively identify all cases that should be included in the registry (Tolusa et al., 2006). In general, the most feasible method of registry data collections calls for the automated extraction of data from electronic health records. Under this approach, the determination of scope is influenced by the data that is readily available in such records systems.

In California, the decision was made to report cases for California residents based on two diagnostic codes from the International Classification of Diseases 10 coding (ICD-10); G20 – Parkinson's Disease/Parkinsonism and G90.3 – Parkinsonism with neurogenic orthostatic hypotension (World Health Organization, 2016; Jankovic et al., 2008). Records were excluded from reporting if patients were non-residents. Summit participants suggested that the full range of neurodegenerative parkinsonisms, as expressed by a greater breadth of ICD-10 codes, would be more useful and revealing because individuals with PD may receive a variety of ICD-10 codes.

Other states, such as Maryland, who are in the process of establishing their own registry, have proposed to broadly align on an ongoing basis with prevailing best practices/bodies rather than express specific case reporting standards at the time of legislative enactment. Bearing in mind that diagnostic criteria and coding will continue to develop, there was strong consensus for leveraging preexisting taxonomic regimes wherever possible. Leveraging the reach and expertise of professional associations (e.g., American Academy of Neurology) or advocacy organizations (e.g., MJFF) can help develop and disseminate trainings which enable effective coding and downstream registry reporting.

Given the high probability that data collection methods, research use cases, and policy interests – not to mention our understanding of PD – will evolve over time, it is prudent for registries to take an expansive view of the definition of Parkinson's disease for data collection purposes. This will help to improve data quality through a more complete identification of individuals with PD and minimize differential identification of PD due to access to care issues exacerbated by a shortfall of movement-disorder specialists. An expansive definition can ease burden on health care providers and data managers by reducing the need for data correction and resubmission in the future when definitions may change.

A Consensus Data Maturity Model For Parkinson's Registries

Creating a PD registry is a complicated and difficult undertaking that requires lots of discussions, planning, and resources. Registries may wish to limit scope initially while anticipating that once the registry is operational, the work can be expanded. This approach is often described as using a maturity model for development and expansion. Starting with the basic data elements to accomplish the initial objectives, the registry can look forward to enhancing data and eventually achieving long-term goals.

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The experiences and studies of Summit participants suggests that there are some basic principles that should be stipulated in the design of a Parkinson's disease registry.

1. Include the data providers in the decision making on what and how to collect data.
2. Minimize or eliminate any extra burden on clinicians and other reporting entities over what they must do to conform with existing data and reporting practices.
3. Make data quality, accuracy, and integrity essential elements of the plan for the Parkinson's disease registry.
4. Maximize the use of electronic health records as the source for data collection.

The choice of what data to collect form a continuum that determines the services that the registry performs or supports. The basic purpose of registries is to determine the incidence and prevalence of Parkinson's within a statewide population. In addition, data components should allow the registry and researchers to determine trends and inequities for public health purposes as well as to perform fundamental data quality activities like deduplicating records. Data quality is critical to improving incidence and prevalence reporting that takes demographics into account (e.g., calculating age-specific PD case rates) and identifies trends and inequities. To accomplish these initial objectives, the Summit developed a set of data components that constitute the basic, minimum set of data that are required.

Once the basic strategy and objectives are met, registries can expand their operations to collect enhanced data and provide additional data services. For example, gathering more data on medications might enable researchers to study the efficacy of drugs on a population scale, or provide better support to identify potential participants for clinical trials.

There are also additional functions that could be performed or supported by the Parkinson's disease registry once it grows beyond the basic and enhanced functionality. At an aspirational maturity level, there is an immense variety of additional data that could be collected and leveraged to improve the lives of people with PD and increase scientific understanding of this complex disease. Further, important research questions pose complex data quality challenges requiring new data models and collection strategies.

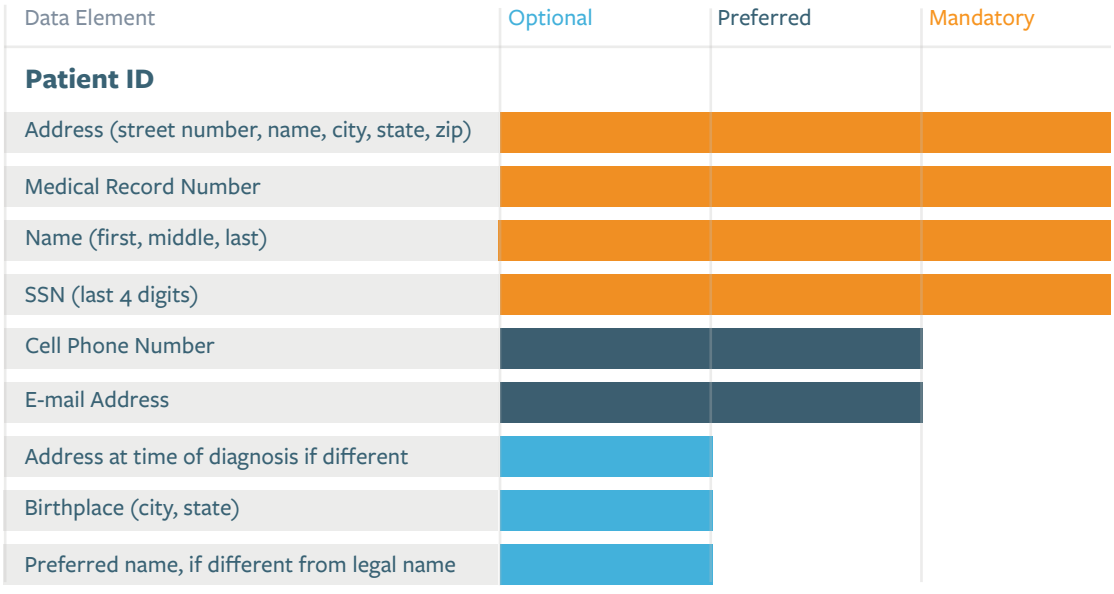
For the purposes of the Summit, the discussion of data components was divided to cover three levels of data maturity: basic, enhanced, and aspirational. The Summit objectives were to seek a consensus on the specific data components or the class of data that would serve each level of maturity. For the aspirational level, it was clear that much more thought was required to identify the particular use cases or scenarios that might constitute the aspirations of each specific registry; example cases and scenarios are provided to guide discussion in states exploring this level of maturity.

Maturity Level 1 - Basic Incidence and Prevalence

Data to be collected initially in a state Parkinson's registry must be sufficient to determine the incidence and prevalence of Parkinson's in the state. Summit participants enumerated a relatively easily collectible minimum set of data elements to be captured by registries through a variety of manual and automated mandatory reporting mechanisms. Detailed technical mechanisms for data collection are outside the scope of this report, but an overview of issues can be found below in *Choosing Sustainable Technology Solutions*.

A Level 1 registry would enable states complete basic monitoring functions and require only a unidirectional flow of data (from providers to registries) but not major clinician workflow changes. Broad, mandatory reporting meets incidence and prevalence needs but also would generally support patient matching and increase the likelihood that longitudinal work could be enabled in subsequent maturity levels.

In supporting statewide monitoring efforts, data collection must include the demographic variables that can help deduplicate case reports, enable analyses of inequities, and deduce trends for various classes of residents such as by age, sex, race, and ethnicity, as well as standardize data to allow comparisons over time and/or across states. The data collection must also help to identify patterns that would help determine causative environmental factors and enable other critical epidemiological analyses that are necessary for public health monitoring. The data should also include basic contact information, both to allow for basic data deduplication and to allow for contact for public health purposes.



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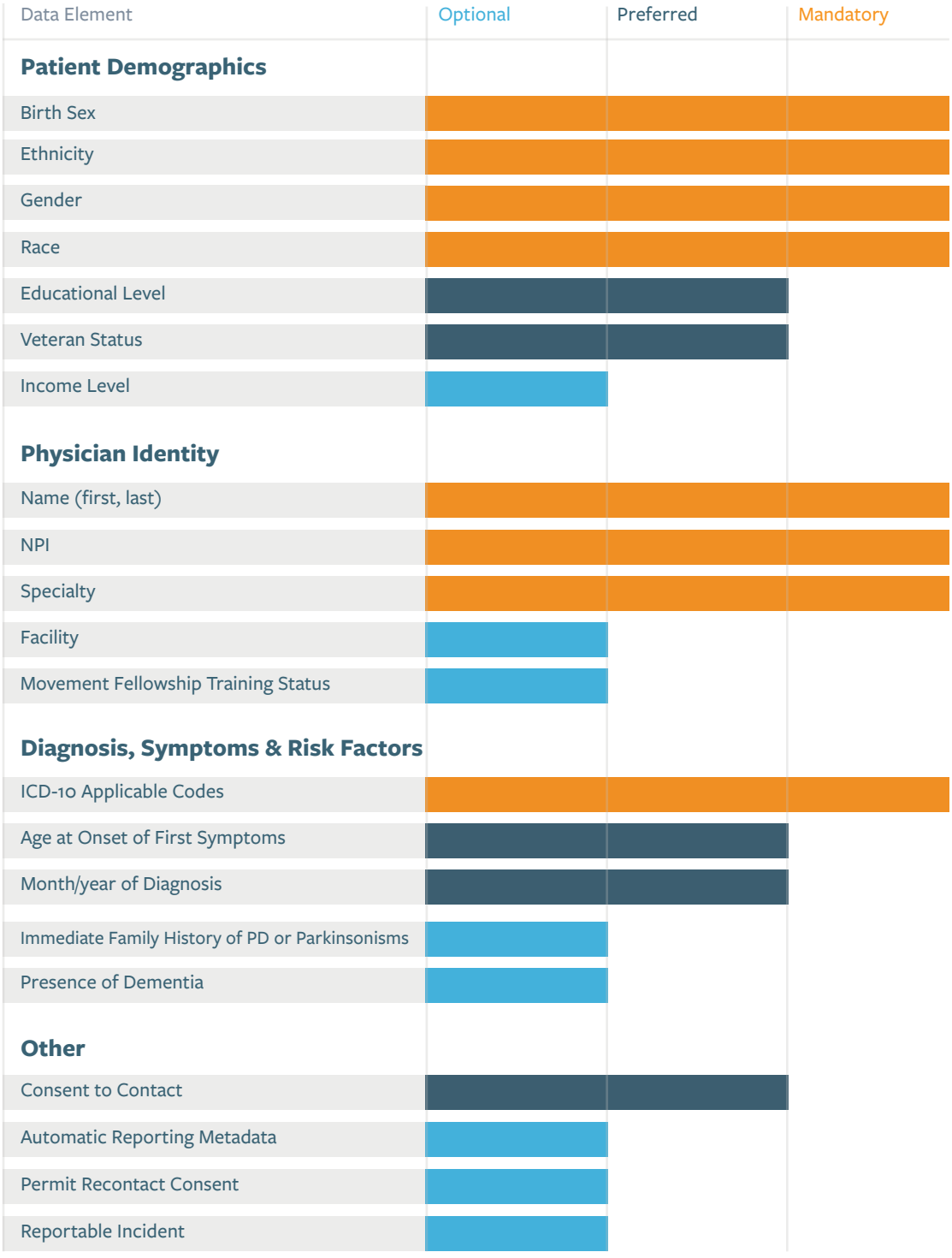


Examples of data elements currently in use or being discussed for usage by active registries are presented in Appendix C.

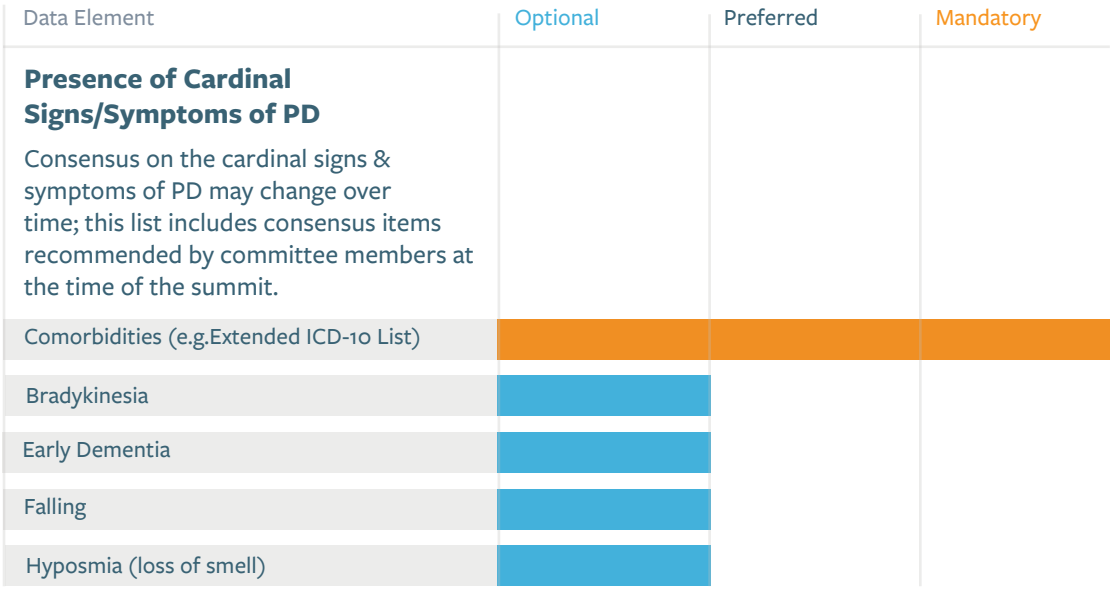
Maturity Level 2 - Enhanced Data Collection

Once a registry is functioning at the basic level of maturity, the opportunity arises to expand its function to facilitate greater research and to provide data on other measures (such as treatment efficacy). As an example, the California Parkinson's Disease Registry has explored new roles in supporting clinical trials and other potential services that could call for enhancing the data collection efforts.

A Level 2 registry would move beyond feasibility and monitoring, to ensure case validation and cohort identification efforts, with a bidirectional flow of data (both to and from registries). Beyond the basic data elements outlined for a Level 1 registry, this would require support for and collection of additional data elements, as well as bidirectional protocols. Given the massive heterogeneity of PD and overlap in diagnostic criteria for parkinsonisms and other neurodegenerative conditions, high-quality case validation would be required for collecting information on the signs, symptoms, and progression of PD. Electronic health records contain considerable information on these items as part of a patient's problem list; this semi-structured data may need to be processed to be useful for a registry's intended purpose, but represent a valuable and largely untapped source of data relevant to PD oversight.

The Massachusetts Parkinson's Registry Advisory Committee explored the potential for enhancing the data collection with other data elements, noting that they may be difficult to collect through electronic transfer. These data elements include: medications (past and present), medical history, UK Brain Criteria diagnosis and PD diagnostic test results such as DATscan, skin biopsy.

Many questions regarding PD remain unanswered around the cause, demographic features, natural history, efficacy of treatments, disease burden, and health economics. Answering these questions is critical for improved treatment, effective resource allocation, and initiatives focusing on disease prevention. Summit participants believe that PD registries can provide an unparalleled opportunity to advance research, taking into account the entire population of people with PD. There are also extended opportunities for registries to provide performance data to data providers about the quality of data, timeliness, and completeness to encourage optimized data entry and thereby improve the utility of registry data for epidemiological and other research purposes.



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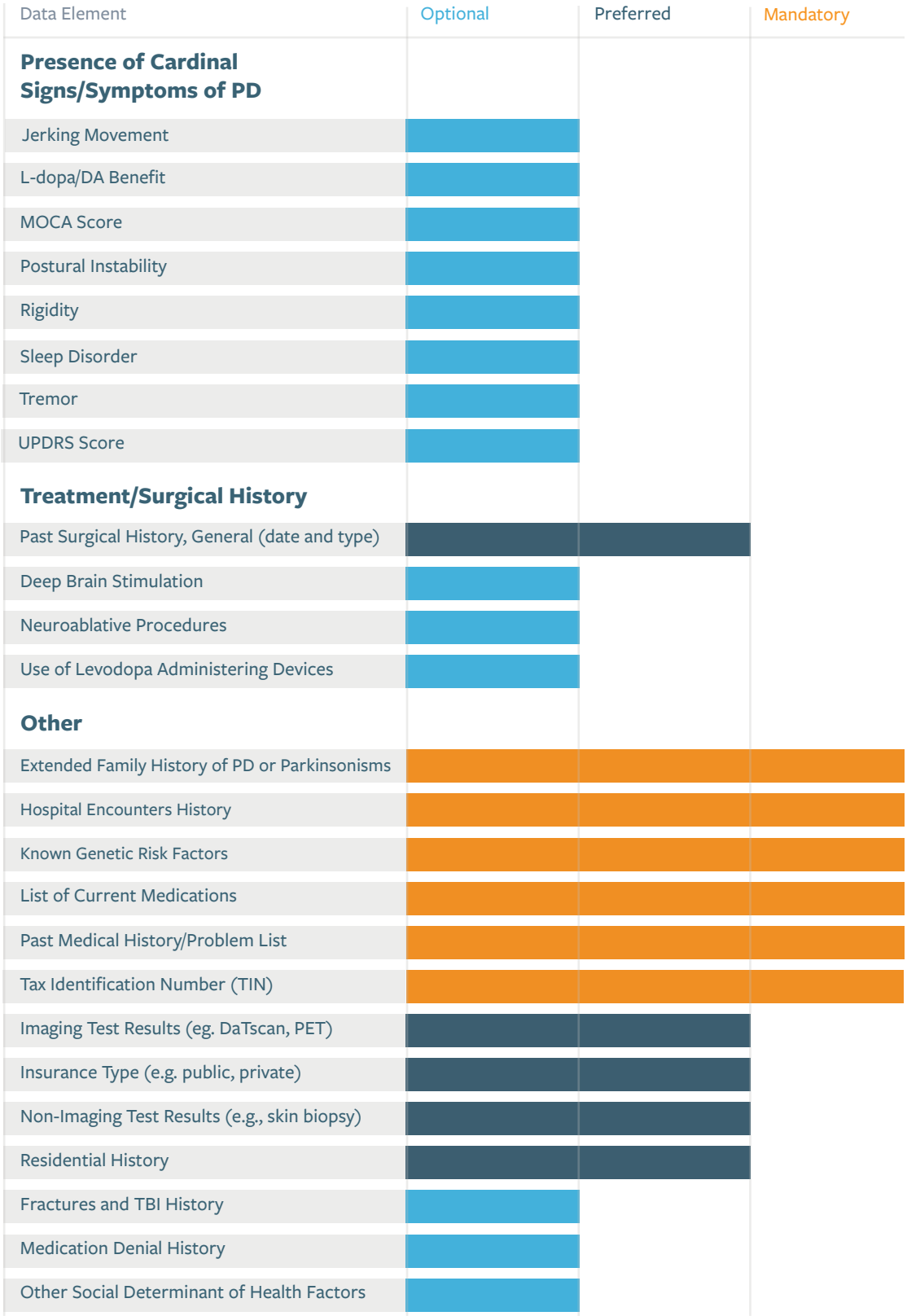

Examples of enhanced data elements discussed for usage by registries in California and Massachusetts are presented in Appendix C.

Maturity Level 3 - Aspirational Data Content

A Level 3 registry, which would require yet further expansion of collected data elements, would function as a key element within a learning health care system. Such a system is one in which internal data and experience are integrated with external data and experience leading to improved knowledge and practice that result in better delivery of care to patients. At this level of maturity, the registry would have integrated support for exchanges with other PD registries and for feedback loops. The aspirational level of maturity for registries involves enormous challenges around data sharing and consolidation. States may find that the data involved is not difficult to collect, but it is difficult to transform so that researchers can take full advantage.

The following sections explore the principles for establishing Level 3 registries and possible enhancements to enable new research and improve utility of the data that is collected, as well as explores in greater depth some of the use cases once operational. The discussion of what data elements represent the full potential of Parkinson's data registries must be based on the potential services that such registries might provide. Researchers have cited aspirations to be able to combine and link case records across state lines, to deduplicate cases across state lines and improve data quality and case definitions, while supporting epidemiological research that is not geographically constrained. Such multi-state data is required for researchers to be able to examine variation in environmental exposures to identify diagnosis and progression risks.

Principles For Level 3 Registries:

As registries mature their level of data collection, the support for research increases accordingly. Particularly when registries begin to include population-based datasets of treatment use including medications, exposures, and outcomes are better defined and measured, research that might otherwise not be possible becomes feasible. Comprehensive data on issues of health care equity will become much more extensive and research findings much more useful in shaping public policy.

Ensure ability to identify external data sources and the means to establish linkages, within states and across state lines. Linking registry data with death records is already in place within at least the California registry, but would be useful if achieved across state lines. Geographic linkages to existing data on environmental exposures and social determinants of health and wellness are also potential components of aspirational levels of maturity for registries. The full development of data linkages would be facilitated by the development of a person identifier (e.g., Global Unique Identifier [GUID]) that could be acknowledged and applied across state lines. Such an identifier would also be the best element for deduplication and for linkage to other registries, CMS, etc. Identifying individuals who had post-mortem pathological assessment and linking registry data with their autopsy findings would be an invaluable resource.

Structure data collection to enable longitudinal studies. Longitudinal collection of individual data, allowing the assessment of individual clinical course in relationship to other registered elements would provide an invaluable resource for research of all types. Included in this principle is the concept of national data availability in accordance with interoperability protocols and domain-specific standards that permit longer term assessments of care and treatments.

Consider research objectives in expanding data collection mandates. There are potential studies that could materially affect the continuum of care and the potential treatment of Parkinson's that cannot be conducted with the limited data currently envisioned for the basic level of maturity or even for the enhanced levels. While such studies require that additional data elements routinely be collected, it will be necessary to collaborate with health systems software providers to expand their interoperable data components to handle additional domain-specific data elements, and to explore new sources of data such as patient reporting.

Possible Enhancements to Enable New Reasearch and Improve Data Utility:

Establish a snapshot of overall health profile, beyond PD. Information on comorbid conditions and concomitant medications not specific to Parkinson's disease, other neurodegenerative conditions, and conditions that may be associated (or confused) with Parkinson's disease (causative or consequence) can be invaluable in avoiding diagnostic misclassification, as well as in understanding the broader syndrome of Parkinson's disease. Information regarding family history or specific genetic information could be very valuable to research and understanding disease determinants and progression but will invoke particularly challenging privacy considerations.

Explore relationship between socioeconomic status and health outcomes. Information on occupation and education (e.g., occupation at diagnosis, longest held occupation, highest educational level attained) would be useful in investigating any relationship between socioeconomic status or specific occupations and Parkinson's disease incidence, disease features, survival, utilization of services, etc. This may also be helpful in identifying and addressing disparities in education, receipt of care, or access to resources.

Enable improved understanding of environmental risk factors through participant location. Adding a geographic localizing element for past residences to allow linkage with environmental monitoring data would be useful in better understanding the relationship between environmental exposures (e.g., pesticides, air pollution, water contaminants) and Parkinson's disease risk and progression. While more difficult to collect than residence at diagnosis alone, a complete residential history provides more complete exposure data that is otherwise near impossible for researchers to obtain at scale. This information can help in identifying needed environmental actions, in identifying and addressing disparities, and in identifying gaps for health education and allocation of resources.

Encourage collection of established instruments. Generally accepted rating scales of disease severity provide benefit to (1) patients hoping to understand their own disease progression, and (2) researchers seeking to understand disease progression and subtyping. If available, Level 3 registries should collect PD-specific instrument results such as from the Hoehn & Yahr Stage or the Unified Parkinson's Disease Rating Scale (MDS-UPDRS), or results from specific cognitive tests such as the Montreal Cognitive Assessment (MoCA) or the Mini-Mental State Exam (MMSE). These are most useful if collected longitudinally and should include evolving patient-reported outcome measures, such as PROMIS measures. Alignment with evolving standard specifications that support PD-related quality registries, such as PD-elements in the AAN Axon Registry, should also be considered.

Provide support for trial recruitment and external study linkages. Allowing registered individuals to indicate an interest in research participation opportunities could be helpful in research study recruitment and better match patients to potentially beneficial clinical trials. Similarly, allowing registered persons to indicate their participation in specific research studies may be useful for long-term understanding of research outcomes.

Use Case 1: Determining Health Care Workforce Needs

States need to plan for the delivery of health care and arrange access to the right care. In addition to estimating the cost of health care burden of Parkinson's (which extends beyond the health care workforce), states are also called upon to collect data to assess disparities in health care and identify at-risk groups. The additional data collected by a level 3 registry could support a more efficient and proactive allocation of resources by quantitatively informing policy decisions. While level 2 of maturity can illuminate demographic disparities, the additional data linkages available at level 3 open complex geographic analyses. For instance, states could potentially compare

PD progression to state-level data on historic chemical exposure, then use current exposure data to predict where risk pockets may arise in the future. They could then invest in building a workforce to meet that need.

In addition, fully assessing the workforce impact of Parkinson's requires ways to collect and link data not only on traditional medical billing, but also on costs incurred by ancillary professional providers and private caregivers. It is important to understand the economic burden associated with all PD caregivers, not just neurologists and other health care providers. Improved data linkages to geographic and occupational job data can highlight access to care disparities and the "hidden" costs of Parkinson's care.

Use Case 2: Cohort Inentification at Scale for Cohort/Clinical Trials

Registries can be leveraged to identify potential trial participants more equitably. By more effectively capturing the diversity of those impacted by Parkinson's disease in a state, registries can help study teams direct strategies and community partnership efforts to address systemic underrepresentation in clinical trial populations. Registries can be a tool for efforts to reduce barriers to trial participation, by helping understand where and how potential participants can be reached. Conversely, by improving our understanding of who is impacted by Parkinson's disease, registries can be helpful to organizers of clinical trials as a trial recruitment mechanism (e.g., through collected contact information) or as a basis for designing an observational study around a particular set of patients (such as around a specific environmental, racial/ethnic or other demographic factor).

Of interest, particularly with aspirational levels of registries, is to equitably identify and recruit cohorts of patients at high risk for developing Parkinson's disease (Berg et al., 2015). Such patients are currently very challenging to identify, limiting ability to conduct clinical trials for patients prior to development of significant symptoms. Further, registries can also be a basis for linking a specific subset of patients to other community resources (e.g., informational materials), interventions, and support mechanisms (not just trials).

Use Case 3: Phenotyping for Precision Medicine

Analysis of data from registries can enable more effective precision medicine. Advances in genetic testing and analysis have led to the application of precision medicine in the treatment of Parkinson's. Expanding access to genetic testing and integrating that data into registries – and coupling with phenotypic data – can lead to a more robust understanding of progression to isolate disease subtypes in pursuit of more tailored and effective treatment. With a population-based data collection, the Parkinson's disease registry can be a source of data to develop better measures for subtyping and more measured ways to describe and predict the progression of the disease.

By expanding access to this information and testing opportunities at scale, patients can more easily understand their journey and the interventional impacts that are possible.

To make them valuable, registries must be sustained over time. Summit participants spoke about important characteristics of a sustainable Parkinson's disease registry: collection of relevant data; information technology/data management experts given a seat at the table during registry establishment; successful partnerships (e.g., hertween EHR companies, registry operators, care providers to jointly develop tools for standardizing reporting); presence of logistical, policy, and communication support (beyond IT/medical expertise); and, protection of patient privacy.

Also discussed was the timeliness of making registry data available to researchers. The conventional way of gathering data, conducting the analysis and resolving duplications, etc., extends this timeline considerably. Under this model, data availability can stretch three to five years, delaying useful conclusions. Some Summit participants were clear that data availability should be assured within one year of a registry's inception.

Building Inclusive and Equitable Data System

Studies have shown notable disparities in data around the care of Parkinson's patients (Dahodwala et al., 2009). Case ascertainment methods have relied on clinical records from academic medical centers which are disproportionately accessed by persons with high income, advanced education, and quality primary care and these characteristics may apply to registry data. Despite significant advances in PD research, most published studies come from the U.S. and Europe, where patient populations are predominantly white and racial/ethnic minorities are underrepresented in both observational studies and clinical trials.

Traditional PD epidemiology studies may be limited in their ability to capture or reflect PD occurring in persons who have language, insurance, geographical, or socioeconomic barriers to enrolling in the study. Registry-based studies built with inclusivity in mind have the potential to overcome this limitation. Registries can provide important opportunities to recognize health disparities and identify risk factors through the collection of sociodemographic, environmental, and clinical data from diverse persons with PD. Equity issues are extremely important in data collection; if registries don't collect data that allow us to identify unique health disparities, data will not help us study or develop interventions for the populations most in need. Below are the NIH-designated health disparity populations that can benefit from more inclusive research conducted on registry data:

- American Indians/Alaska Natives, Asian Americans, Blacks/African Americans, Hispanics/Latinos, Native Hawaiians, and Pacific Islanders
- Sexual and gender minorities
- Socioeconomically disadvantaged populations
- Underserved rural populations

Maintaining Legislative and Financial Support

Convincing state legislatures to create and fund a Parkinson's disease registry is sometimes just a matter of explaining what such a registry can do to illuminate the problems of coping with and treating Parkinson's within a state, including the economic impact. Legislatures seem to know that with the aging of populations, the incidence of Parkinson's increases, and there are health care costs to consider as well as the quality of life for people with PD. Gaining legislative support is easier when there is a patient advocacy organization supporting the concept or a coalition of service providers who see the value in such a concept.

Existing and emerging Parkinson's disease registry programs have shown their value and made it clear that the statutes enabling the creation of a Parkinson's disease registry must not have an expiration date. Starting a registry as an experiment or pilot with an end date means that staff will not be motivated to take the kind of long

view that is needed for this work, and the flow of funds for maturing a registry will not be available. Registry operators need to develop a strong statement of value to ensure sustainable funding. In California, considerable support for developing and establishing value came from advocacy groups that saw the need and persuasively argued before the legislature. Use cases, such as the ability to support telemedicine and engage remotely for data collection, are helpful in articulating the value premise.

Legislation derived from the model contained in Appendix B to this report is a starting point for states to modify to their own situations.

Choosing Sustainable Technology Solutions

Protecting Registrant Privacy

Critical to provider and patient participation is commitment to the highest level of privacy protection consistent with state and federal privacy laws. Summit attendees concurred that privacy concerns amongst patients persist, but that through adherence with preexisting legal regimes these concerns could be sufficiently addressed to collect data and meet each maturity level's respective goals. Developing and refining communications strategies and plans for addressing historically underrepresented or skeptical populations previously impacted by privacy breaches is critical to capturing a representative set of patients.

Navigating the Maze of Data Standards

Examples of health IT standards with relevance to PD registries. Examples vary in terms of maturity and scope. Red items are of particular interest for PD registries; italicized items are less established or more limited in scope. Office of National Coordinator (ONC)-supported list of interoperability standards can be found at https://www.healthit.gov/isa/

Health IT Standards

Examples of health IT standards with relevance to PD registries. Examples vary in terms of maturity and scope. Red items are of particular interest for PD registries; italicized items are less established or more limited in scope. Office of National Coordinator (ONC)-supported list of interoperability standards can be found at https://www.healthit.gov/isa/

Framework standards Network of networks	**Data Exchange Standards** Standards for interoperable data
eHealth Exchange CommonWell Health Alliance CareQuality network TEFCA (for QHINs, Sequoia Project) Frameworks with CDM: OMOP-CDM, i2b2, PCORnet Domain-specific frameworks with CDM: NPCR (cancer), eMerge (genomics) AMP-PD (PD research) NNCSS (PD surveillance)	USCDI (v1 2020; v3 2022) HL7 exchange standards: HL7 v3 (CDA, C-CDA) HL7 eCR standards (used by CPDR) HL7 FHIR standards Domain-specific exchange standards: USCDI+ (announced Sep 2018) domain-specific FHIR resources Quality: eCQM, dQM Clinical decision support standards: CDS Connect, CDS Hooks

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Concept Standards
vocabularies, terminologies, ontologies

ICD10: diagnoses
CPT: procedures
RxNorm/NDC: medications
LOINC: labs/observations
SNOMED-CT: medical ontology
ORMIS-PD (PD ontology, in development)

Groupings of concepts:
VSAC: valueset (concept) repositories
OHDSI/OMOP standard vocabulary
IMO: vendor for medical vocabularies
NLM Metathesaurus

Domain (PD)-specific data standards:
State registry data specifications (e.g. CPDR)
PD epidemiology cohort specifications (e.g. PEG, CPDR pilot)
NINDS PD CDE (research)
Clinical rating scales: UPDRS, H&Y, PDQ39, etc

Network standards
Health information exchanges and registries

Local/Regional/State HIEs
see CAHIE (for many California HIEs)
Vendor HIEs:
e.g. Care Everywhere, Epic; Cerner HIE
Qualified Health information Networks (QHIN)

State PD registries (e.g. CPDR)
PD Research Registries:
Parkinson Foundation Patient Registry
PPMI, PDGene, GP2, others

Quality registries: Axon Registry (AAN)
Public health: APHL (eCR, Digital Bridge)

Contributed by Allan Wu

Concept standards are notable for the disparate specifications that exist for various use cases, and suggest an opportunity for development of a domain-specific data dictionary or ontology for PD. Another data standard that is of direct interest to registries is the U.S. Core Data for Interoperability (USCDI) model (see Appendix D for USCDI data elements) which serves as the required interoperability floor of elements that all certified electronic health records must support and interchange. The HL7 eCR (electronic case report) standard, previously discussed, has great potential to facilitate automated public health reporting and could be a high priority to support for PD registries.

The Trusted Exchange Framework and the Common Agreement (TEFCA) is the current, evolving, HHS Office of the National Coordinator for Health IT supported standard for national interoperability. TEFCA consists of data exchange principles, rules, and technical specifications which Qualified Health Information Networks (QHIN) implement. Each QHIN may connect to any number or types of entities. TEFCA has yet to be implemented, but the first QHINs are anticipated to begin use in 2023, focused on infectious diseases.

PD registries can contribute to the expansion, consensus building, and use cases for many of the above standards to assure greater usefulness in the PD registries context. For example, the USCDI standard is continuing to gain traction, with the recently announced USCDI+ initiative developing domain-specific extensions. PD-specific extensions could become a priority if the PD registry community adopted USCDI broadly. Or, given that the initial TEFCA use cases hinge on public health interoperability, state PD registries may be a novel opportunity to contribute a non-infectious disease example to the discussion and contribute to a development roadmap.

Alignment with standards established for non-registry purposes can benefit registries. In 2009, the National Institute of Neurological Disorders and Stroke (NINDS), part of the NIH, convened the Parkinson's Disease v1.0 Common Data Elements (CDE) Working Group. In 2021, a new working group was convened to create v2.0, which was published in August 2022 (for further discussion, see Appendix E). As registries progress to maturity level 2 and level 3 which require an expanded number of data elements, drawing upon (and aligning with) preexisting data standards such as the NINDS CDEs will enable stakeholders at various registries to maximize interoperability by leveraging this shared and commonly accepted standard.

Recommendations For Policymakers

1. **Define "Parkinson's disease" broadly for the purpose of automated data collection.** Registries should seek to allow data collection on cases of Parkinson's disease and related neurodegenerative diseases. The basic level of reportable cases may be those where the ICD-10 diagnosis codes in the record address Parkinson's disease or parkinsonisms. As data collection is enhanced, symptoms such as tremors and other factors such as medications prescribed become useful predictive indicators of disease progression. For registries that expand reporting requirements beyond Parkinson's disease (e.g., degenerative neurologic conditions) there will be a need to expand the list of ICD-10 and/or SNOMED codes accordingly. Engaging disease specific organizations and neurologists in this process will be important to recommend a consensus set of trigger codes for reporting.
2. **Expand the number of state Parkinson's Registries to ensure a broad cross section of the United States population is represented.** The more states that create a PD registry, the more complete our understanding of PD can become. To identify health disparities and meet public health challenges, it is critical that as many states as possible join in this effort. Successful implementation of registries throughout the United States and their sustainability are dependent on the support obtained by creating a lasting partnership with the primary stakeholder groups who provide data, advocate for knowledge about the disease, and do the research leading to improved patient care.
3. **Enact policies and programs that address the shortage of qualified health care experts necessary for the success of a PD registry.** Plans and programs to create and sustain registries must deal with the reality of a shortage of care providers (who collect registry data) and data analysts (who interpret registry data) as well as other key labor categories in health care and public health.
4. **Consider health equity challenges when enacting registry legislation.** Registries will benefit from taking into account issues of health equity in designing data collection processes. Engaging with local community equity programs and integrating joint reporting will provide further support for sustaining registry operations.

Recommendations For Implementing Bodies

1. **Create a clear statement of value for your jurisdiction's registry.** Registry management must develop clear definitions of the value premise of registries. It is helpful to describe and implement use cases such as those presented in this report, and to articulate the research benefits of population-based registries.

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2. **Reduce data entry burden on data providers, where feasible.** To increase the likelihood of success, at Level 1 of registry maturity, data providers using electronic health records should not be required to do anything outside their normal workflow to report notifiable conditions, such as Parkinson's disease, to state public health registries. At higher levels of maturity, implementing bodies should seek to take advantage of existing data collection workflows whenever possible and to minimize the additional burden on data providers.. Depending on the planned data collection mechanisms (e.g., automated EHR reporting, manual reports), states should consult with impacted stakeholder groups.

3. **Adopt best practice data standards to increase interoperability.** Adoption of national standards for case reporting is essential to long term success. The collection of basic data (e.g., demographics) and detailed information that exists in standard formats on the medical record (e.g., laboratory results, immunizations, medications) should, when possible, be transmitted using the HL7 consensus standard (eICR) for public health reporting, or a similar data standard. This standard allows the automated collection of information for all notifiable conditions such that health care providers need not do anything outside of their normal workflow. Authorizing legislation for state registries should refer to this HL7 standard as an acceptable/preferred way that sources can send reports to public health authorities. Data standards should also support the various layers of interoperability that are essential to successful operation of registries. Registry databases must be linkable to other repositories such as mortality records, environmental databases, social determinants of health, etc.

4. **Establish a working group of officials from states with enacted registry legislation to increase collaboration and knowledge transfer between jurisdictions**. Summit participants agreed that further communications between the state registries and their consideration of needs expressed by the research community would optimize strategy and standardization to further understanding of Parkinson's and treatment. Formalizing such communications through the creation of a working group was deemed worthy of further consideration by the appropriate stakeholders. An example of such a structure might be the formation of an association of Parkinson's disease registry directors.

Recommendations For Stakeholders & Advocates

1. **For healthcare provider professional associations: Establish tools and training to improve problem list data entry quality.** Registries, MJFF, patient advocacy groups, and researchers should work with the neurology community to encourage documentation of Parkinson's disease and its signs and symptoms in patients' problem list to assure complete reporting of the disease. Recognizing that these may be a burdensome requirement for care providers, professional associations should consider technological solutions that will reduce data entry burden and keep the problem list useful in clinics.

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2. **For health care technology providers: Develop and publish toolkits to standardize data collection regarding PD signs and symptoms.** The collection of currently unstructured data to be used in case validation (e.g., information on Parkinson's signs and symptoms) can be considered for secondary data collection from interested parties (e.g., participating neurologists) who agree to collect this additional information and record it in a standardized manner. This would require a partnership of healthcare informaticists, vendors of electronic health records, reporting entities, registry officials and researchers. Consideration of including Standard Development Organizations such as HL7 might be considered.

3. **For advocacy organizations: Establish an advisory council to regularly review diagnosis code lists and advise registries on best practices.** A group of neurologists and health care informaticists should evaluate the current list of Counsel of State and Territorial Epidemiologist (CSTE) ICD-10 and SNOMED codes for triggering the report of Parkinson's disease and parkinsonisms for completeness and accuracy. If the list of codes needs to be altered, then the group should contact CSTE to recommend and discuss potential changes. Registries should work with Parkinson's disease organizations and legislators to initiate or change reporting requirements in legislation or regulation accordingly.

4. **For states with, or interested in, registries: Regularly convene a consortium to develop best practices.** Such a group could develop and maintain a living document that outlines a playbook for initiating, building, and managing a PD registry. Involving patients in the consortium and its processes would promote buy-in from the ground up, as would a commitment to continued review and revision of the maturity model outlined here. Additionally, a consortium could agree to data collection standards and address issues such as around diagnostic codes and technology challenges and others that emerge.

5. **For The Michael J. Fox Foundation: Continue to act as a convener and work to develop and disseminate educational materials to facilitate the establishment and sustainability of state registries.** As an immediate follow-up to the workshop described in this report, MJFF should convene a technical meeting to discuss technical solutions for PD registries including reporting, receipt and ingestion of data, management formats, security, and data sharing. Vendors of health IT, healthcare CMIOs/informaticists, CDC, CMS, and ONC represent potential participants. There is a significant need for education for the public as well as for clinicians. The Foundation should continue to bring attention to the National Plan to End Parkinson's, a bill introduced to Congress that would require HHS to carry out a project to prevent and cure Parkinson's disease.

Conclusion

Attendees at the Summit agreed wholeheartedly that states are interested in developing Parkinson's disease registries as a major source of support for Parkinson's-related research. For registries to provide maximum utility, states should take advantage of the maturity models recommended herein, including the lists of suggested data elements.

Ultimately, the success of registries will be dependent on integration of diverse stakeholder views, a commitment to collaboration, and sustained support from lawmakers. Ensuring buy-in and clear value-adds for those involved will enable registries to not only support desired research and policy goals but also overcome the challenges pertaining to data quality, collection, privacy, distribution, and utility. Working together at the intrastate, interstate, and national levels can provide ever-increasing value to the research and patient communities.

Some of the states that attended the National Summit are in the early stages of establishing registries and beginning to implement data collection programs. These states will need further encouragement and support from colleagues as they proceed. MJFF plans to continue its efforts to help states begin to create Parkinson's disease registries along the lines of the capabilities and standards outlined at this Summit. It is likely that additional states will choose to begin this work in the coming months and years. MJFF and Summit participants look forward to future collaboration opportunities to build a better registry future, together.

Appendix A. Summit Participants

Name	Affiliation
Esther Ndemo	American Academy of Neurology - Axon Registry
Karen Lundgren	American Academy of Neurology - Axon Registry
Rebecca Gilbert, MD, PhD	American Parkinson's Disease Association
Cathi Thomas, MSN, RN	Boston University
Jeremy Pine	California Registry
Mark Damesyn, DrPH, MPH	California Registry
Satya Sahoo, PhD	Case Western University
Laura A. Conn	Centers for Disease Control and Prevention
Shawna Mercer, PhD	Centers for Disease Control and Prevention
William MacKenzie, MD	Centers for Disease Control and Prevention (Ret.)
Jeanette Stingone, PhD	Columbia University
Jessica Rose-Malm	Maryland Department of Health
Kristi Pier	Maryland Department of Health
Grace Kranstover	Michael J. Fox Foundation for Parkinson's Research
Josh Gottesman	Michael J. Fox Foundation for Parkinson's Research
Julia Worcester, JD	Michael J. Fox Foundation for Parkinson's Research
Leslie Kirsch, EdD	Michael J. Fox Foundation for Parkinson's Research
Mason Zeagler	Michael J. Fox Foundation for Parkinson's Research
Ted Thompson, JD	Michael J. Fox Foundation for Parkinson's Research
Zach Hardy	Michael J. Fox Foundation for Parkinson's Research
Ernad Klipic	Nebraska Registry
Jill Krause	Nebraska Registry
Allan Wu, MD	Northwestern University
Anna Naito, PhD	Parkinson's Foundation
Jim Beck, PhD	Parkinson's Foundation
Zachary Meyer	Parkinson's Foundation
Codrin Lungu, MD	Pfizer
Gonzalo J. Revuelta, DO	South Carolina Registry
Lori McMahon, PhD	South Carolina Registry
Andrew Wilson, MD, MS, MBA	University of California Los Angeles
Irene Litvan, MD	University of California San Diego
Caroline Tanner, MD, PhD	University of California San Francisco
Sarah Benis , MD, FAAN	University of Minnesota
Whitley Aamodt, MD	University of Pennsylvania
Allison W. Willi , MD	University of Pennsylvania
Ray Dorsey, MD	University of Rochester
Deepak Gupta, MD, MS	University of Vermont
Susan Nielsen, PhD	Washington University in St. Louis
Paul Wormeli	Wormeli Consulting
Beth Mastin	West Virginia Registry/West Virginia University
Helen Matheny	West Virginia Registry/West Virginia University
Padmashree Tirumalai, PhD	West Virginia Registry/West Virginia University
Rochelle Goodwin, JD	West Virginia Registry/West Virginia University
Victor Finomore, PhD	West Virginia Registry/West Virginia University

Appendix B. Model Legislation

Disclaimer: The below language is concept language and is not the only pathway for a state to enact a Parkinson's disease registry. This language may also be altered in future years to meet modern statutory requirements and legislative needs.

An Act establishing a State Parkinson's Disease registry.

SECTION 1. Chapter ___ is hereby amended by adding the following section:

Section __. (a) The department of health shall collect data on the incidence of Parkinson's disease in STATE NAME and other epidemiological data as defined in this Act. For the purposes of this section, "Parkinson's disease" means a chronic and progressive neurologic disorder resulting from deficiency of the neurotransmitter dopamine as the consequence of specific degenerative changes in the area of the brain called the basal ganglia. It is characterized by tremor at rest, slow movements, muscle rigidity, stooped posture, and unsteady or shuffling gait. "Parkinsonisms" means related conditions that causes a combination of the movement abnormalities seen in Parkinson's disease — such as tremor at rest, slow movement, muscle rigidity, impaired speech or muscle stiffness — which often overlap with and can evolve from what appears to be Parkinson's disease. Example Parkinsonisms of particular interest include, but are not exclusive to, the following: Multiple System Atrophy (MSA), Dementia with Lewy Bodies (DLB), Corticobasal Degeneration (CBD), and Progressive Supranuclear Palsy (PSP). The registry and system of collection and dissemination of information shall be under the direction of the commissioner, who may enter into contracts, grants or other agreements as are necessary for the conduct of the program.

(b) All patients diagnosed with Parkinson's disease or related Parkinsonisms, as advised by an Advisory Committee, shall be provided a notice in writing and orally regarding the collection of information and patient data on Parkinson's disease. Patients who do not wish to participate in the collection of data for purposes of research in this registry shall affirmatively opt-out in writing after an opportunity to review the documents and ask questions. No patient shall be forced to participate in this registry.

(1) The department shall establish a Parkinson's Disease Registry Advisory Committee to assist in the development and implementation of the registry; determine what data shall be collected; and generally, advise the department.

(2) Membership of the committee must include representation from

A. a neurologist,
B. a movement disorder specialist,
C. a primary care provider,
D. a physician informaticist,
E. a patient living with Parkinson's Disease,
F. a public health professional,
G. a population health researcher familiar with registries,
H. a Parkinson's Disease researcher,
I. anyone else the department deems necessary.

(c) The department shall establish a system for the collection and dissemination of information determining the incidence and prevalence of Parkinson's disease and related Parkinsonisms, as advised by an Advisory Committee. The department shall designate Parkinson's disease and related Parkinsonisms as advised by an Advisory Committee as diseases required to be reported in the state or any part of the state. All cases of Parkinson's disease diagnosed or treated in **STATE NAME** shall be reported to the department. However, the mere incidence of a patient with Parkinson's shall be the sole required information for this registry for any patient who chooses not to participate. For the

subset of patients who choose not to participate, no further data shall be reported to the registry. The department may create, review and revise a list of data points required as part of mandated Parkinson's disease reporting under this Section.

i. This list shall include, but not be limited to, necessary triggering diagnostic conditions, consistent with the latest International Statistical Classification of Diseases and Related Health Problems, and resulting case data including, but not limited to, diagnosis, treatment and survival.

ii. The department may implement and administer this subdivision through a bulletin, or similar instruction, to providers without taking regulatory action.

(d) The department shall provide notification of the mandatory reporting of Parkinson's disease and Parkinsonism on its website and may also provide that information to professional associations representing physicians, nurse practitioners, and hospitals at least 90 days prior to requiring information be reported.

(e) A hospital, facility, physician, surgeon, physician assistant and nurse practitioners who diagnose or are responsible for providing primary treatment to Parkinson's disease or Parkinsonism patients shall report each case of Parkinson's disease and Parkinsonisms to the department in a format prescribed by the department. The Department shall be authorized to enter into data sharing contracts with data reporting entities and their associated electronic medical record systems vendors to securely and confidentially receive information related to Parkinson's disease testing, diagnosis and treatment.

(f) The department may enter into agreements to furnish data collected in this registry to other states' Parkinson's disease registries, federal Parkinson's disease control agencies, local health officers, or health researchers for the study of Parkinson's disease. Before confidential information is disclosed to those agencies, officers, researchers, or out-of-state registries, the requesting entity shall agree in writing to maintain the confidentiality of the information, and in the case of researchers, shall also do both of the following:

i. obtain approval of their committee for the protection of human subjects established in accordance with Part 46 (commencing with Section 46.101) of Title 45 of the Code of Federal Regulations; and

ii. provide documentation to the department that demonstrates to the department's satisfaction that the entity has established the procedures and ability to maintain the confidentiality of the information.

(g) Except as otherwise provided in this section, all information collected pursuant to this section shall be confidential. For purposes of this section, this information shall be referred to as confidential information. To ensure privacy, the department shall promulgate a coding system that removes any identifying information about the patient.

(h) Notwithstanding any other law, a disclosure authorized by this section shall include only the information necessary for the stated purpose of the requested disclosure, used for the approved purpose, and not be further disclosed.

i. Provided the security of confidentiality has been documented, the furnishing of confidential information to the department or its authorized representative in accordance with this section shall not expose any person, agency or entity furnishing information to liability, and shall not be considered a waiver of any privilege or a violation of a confidential relationship.

(j) The department shall maintain an accurate record of all persons who are given access to confidential information. The record shall include: the name of the person authorizing access; name, title, address, and organizational affiliation of persons given access; dates of access; and the specific purpose for which information is to be used. The record of access shall be open to public inspection during normal operating hours of the department.

(k) Notwithstanding any other law, confidential information shall not be available for subpoena, shall not be disclosed, discoverable or compelled to be produced in any civil, criminal, administrative or other proceeding. Confidential information shall not be deemed admissible as evidence in any civil, criminal, administrative or other tribunal or court for any reason.

This subsection does not prohibit the publication by the department of reports and statistical compilations that do not in any way identify individual cases or individual sources of information.

Notwithstanding the restrictions in this subsection, the individual to whom the information pertains shall have access to his or her own information.

(l) This section does not preempt the authority of facilities or individuals providing diagnostic or treatment services to patients with Parkinson's disease to maintain their own facility-based Parkinson's disease registries.

SECTION 2. [Ongoing reports]
And be it further enacted, that, on or before January 1, 2024, and every year thereafter, the STATE HEALTH DEPARTMENT shall report to RELEVANT LEGISALTIVE BODY/COMMITTEES, a yearly program summary update on the incidents and prevalence of Parkinsons's in the state by county, how many records have been included and reported into the registry, and demographic information such as patients by age, gender and race. This yearly report shall also be published in a downloadable format on the State's Health Department Webpage or designated STATE PARKINSON'S RESEARCH REGISTRY WEBPAGE.

- Example of State Fact Sheet: California Summary Report - April 2022

SECTION 3. [State Webpage]
And be it further enacted that, on or before XXXX DATE, and every year thereafter, the STATE HEALTH DEPARTMENT shall create and maintain a webpage called STATE (include state name) PARKINSON'S RESEARCH REGISTRY where the public can go for information related to registry, a yearly program summary, and any other relevant or helpful information related to the registry as deemed necessary by the Advisory Council.

SECTION 4. [language about effective date]

- Preferred effective date for Advisory Committee to be established is within 90 days of Governor's signature, or standard state effective date (such as July 1 for fiscal year).
- Preferred date for Infrastructure of Registry to go live for collecting reporting data is 12 months/1 year from Governor's signature or one year from effective date of legislation. For example, if the bill becomes effective within 30 days of the Governor's signature, then the registry should be live by 12 months from that date.
- Preferred date for Advisory Committee to report recommendations to Department and Legislature is: First Report by end of Calendar Year, ongoing reports on a yearly basis and published on a dedicated website within the main website of Department for public to view years data trends.

NOTE: Section D notes that the state should give health care providers notice of mandatory reporting 90 days before the mandate goes into effect. In terms of the overall law, it can become effective whenever but there should be time built in (6 months to 1 year) for the department to build out the registry which could include issues such as securing consultants with expertise to advise the department, hiring staff to implement and manage the registry, etc.

Appendix C. Data Elements Currently In Use Or Discussion By Active Registries

For comparison purposes, the following table depicts the **basic data** elements selected by California and Massachusetts for their Parkinson's disease registries:

		California	Massachusetts
Data Content Area	**Field**	**Required** [vii]	**Required** [viii]
Patient ID			
	Patient Name, First	+	+
	Patient Name, Last	+	+
	Patient Name, Middle Initial	+	+
	Date of Birth	+	+
	Sex - (Gender)	+	+
	Patient Street Address (Street & No.)	+	+
	Patient Address City	+	+
	Patient Address State	+	+
	Patient Address Zip (Postal) Code	+	+
	Social Security Number	+	+ (at least last 4 digits)
	Medical Record Number - MRN	+	+
Patient Demographics			
	Race	+	+
	Ethnicity	+	+
	Date Last Contact/ Death		
Physician Identifiers (Primary)			
	Physician Name, First	+	
	Physician Name, Last	+	
	Author NPI - Physician ID	+	

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Appendix

		California	Massachusetts
Data Content Area	**Field**	**Required** [vii]	**Required** [viii]
Physician Identifiers (Primary)			
	Physician Specialty	+	
	Physician Street Address	+	
	Physician City	+	
	Physician State	+	
	Physician Zip (Postal) Code	+	
	Physician email	+	
	Physician License Number	+	
Primary Diagnosis			
	ICD-10/Diagnosis Term	+	
	Month/Year of Diagnosis	+	
Disease Onset			
	Onset Date		+
	Symptoms at Onset		
Patient Information			
	Date of Diagnosis		+
	Confirmed by Neurologist (Y/N)		+
	Age at Onset		+
	Does Patient have 1st degree relative with Parkinson's		+
	Moderate to vigorous exercise of 150min/wk (Y/N)		+
	Presence of dementia of mild cognitive impairment		+

Appendix

For comparison purposes, the following table depicts the enhanced data elements considered by California and Massachusetts for the enhanced maturity level of data collection.

Enhanced Parkinson's Data Components

Cardinal Signs / Symptoms of PD

+ Resting Tremor
+ Tremor
+ Shaking
+ Jerking movements
+ Trembling
+ Bradykinesia
+ Slowness
+ Slow movements
+ Cogwheel rigidity
+ Rigidity
+ Stiffness
+ Tightness
+ Postural Instability
+ Falling
+ Loss of Balance
+ Difficulty in Maintaining Balance
+ Unstable Gait
+ Stumbling
+ Unsteadiness
+ Asymmetry, at onset
+ Dysfunction (tremor, bradykinesia or rigidity) more pronounced on one side of body than the other
+ More difficulty moving one side of the body than the other
+ Assymmetry, ever (only if Asymmetry at onset is not available)
+ L-dopa/DA benefit
+ > 1 year of continuous therapy
+ Progressive Disorder
+ Early dementia (preceding motor symptoms or in the first year after diagnosis)

Surgical Treatments

+ Deep Brain Stimulation
+ Neuroablative Procedures

Current Medication 1 (fields may repeat, Med 1, Med 2,.....)

+ Medication Class Reference
+ Medication Name Reference
+ Medication Dose
+ Medication Frequency
+ Medication Use Ongoing

Past Medication 1 (fields may repeat, Med 1, Med 2,.....)

+ Medication Class Reference
+ Medication Name Reference
+ Medication Dose
+ Medication Frequency
+ Medication for Discontinuation

Appendix D. U.S. Core Data For Interoperability (USCDI) Standards

United States Core Data for Interoperability (USCDI) Standards

+ Federal data standards for data content areas and specific data elements
+ Data content areas and specific data elements are defined as FHIR resources

USCDI v2 Summary of Data Classes and Data Elements

Allergies and Intolerances	
+ Substance (Medication) + Substance (Drug Class)	+ Reaction
Assesment & Plan of Treatment	
+ Assessment and Plan of Treatment	+ SDOH Assessment
Goals	
+ Patient Goals	+ SDOH Goals
Care Team Member(s)	
+ Care Team Member Name + Care Team Member Identifier + Care Team Member Role	+ Care Team Member Location + Care Team Member Telecom
Clinical Notes	
+ Consultation Note + Discharge Summary Note	+ History & Physical + Progress Note
Clinical Tests	
+ Clinical Test	+ Clinical Test Result/Report
Diagnostic Imaging	
+ Diagnostic Imaging Test	+ Diagnostic Imaging Report
Encounter Information	
+ Encounter Type + Encounter Diagnosis + Encounter Time	+ Encounter Location + Encounter Disposition
Health Concerns	
+ Health Concerns	
Immunizations	
+ Immunizations	

Continued on next page

USCDI v2 Summary of Data Classes and Data Elements Continued

Laboratory

+ Tests
+ Values/Results

Medication

+ Medication

Patient Demographics

+ First Name
+ Last Name
+ Previous Name
+ Middle Name (including Middle Initial)
+ Suffix
+ Sex (Assigned at Birth)
+ Sexual Orientation
+ Gender Identity
+ Date of Birth
+ Race
+ Ethnicity
+ Preferred Language
+ Current Address
+ Previous Address
+ Phone Number
+ Phone Number Type
+ Email Address

Problems

+ Problems
+ SDOH Problems/HealthConcerns
+ Date of Diagnosis
+ Date of Resolution

Procedures

+ Procedures
+ SDOH Interventions

Provenance

+ Author Time Stamp
+ Author Organization

Smoking Status

+ Smoking Status

Unique Device Identifier(s) for a Patient's Implantable Device(s)

+ Unique Device Identifier(s) for a Patient's Implantable Device(s)

Vital Signs

+ Diastolic Blood Pressure
+ Systolic Blood Pressure
+ Body Height
+ Body Weight
+ Heart Rate
+ Respiratory Rate
+ Body Temperature
+ Pulse Oximetry
+ Inhaled Oxygen Concentration
+ BMI Percentile (2-20 Years)
+ Weight-for-length Percentile (Birth-36 Months)
+ Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

Contributed by Jeremy Pine

Appendix E. NINDS Parkinson's Disease CDE Working Group

The objectives of the CDE WG are more applied to research projects than the kinds of surveillance work normally performed by a Parkinson's disease registry. Their objectives are:

- To reduce study start-up time and accelerate data sharing in neuroscience
- Develop and update data standards for clinical research
- Increase the efficiency and effectiveness of clinical research studies and clinical treatment, increase data quality, facilitate data sharing and help educate new clinical investigators
- PD CDEs version 2.0: additions and revisions based on developments in the field of Parkinson's disease research, to ensure that the CDEs remain a current and useful tool for investigators and their research teams.

The general elements contained in their standard are explained in the following:

CDE Data Element Classification

- **General Core:** A data element that is required for NINDS funded studies.
- **Disease Core:** A data element that collects assential information applicable to any disease-specific study, including all therapeutic areas.
- **Supplemental - Highly Recommended:** A data element which is essential based on certain conditions or study types in clinical research studies.
- **Supplemental:** A data element which is commonly collected in clinical research studies.
- **Exploratory:** A data element that requires further validation, but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete.

Contributed by Codrin Lungu

The full description of the extensive list of CDE content is available on the NIH website at: https://www.commondataelements.ninds.nih.gov/Parkinson's%20Disease.

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