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Recommendations for Addressing Technological Requirements for Statewide Parkinson's Disease Registries


THE MICHAEL J. FOX FOUNDATION
FOR PARKINSON'S RESEARCH

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Purpose and Acknowledgments

The 2023 Parkinson's Disease Registry Technology Summit, organized by The Michael J. Fox Foundation for Parkinson's Research (MJFF), focused on the technological requirements necessary for the establishment, operation, enhancement and ongoing maintenance of statewide Parkinson's disease (PD) registries. It built on a summit held in the fall of 2022, which centered on building consensus around the common data elements that should be included in such registries in accordance with their level of maturity to meet an array of public health needs and research goals. To consider the multifaceted nature of such efforts, MJFF convened an array of stakeholders of varying expertise, including:

Rather than making recommendations for specific technology solutions, the 2023 summit sought to build awareness of the considerations that stakeholders should be mindful of in planning their registry operations. This included:

- Registry workflow design to understand the data lifecycle from capture to analysis
- Registry interoperability and integration considerations, to maximize the lifespan of registries as standards and technologies continue to emerge
- A variety of stakeholder interactions to ensure registry design meets the needs of all involved
- The importance of good data governance, as well as the risks and mitigation strategies from both a technology and oversight perspective
- Key technology infrastructure requirements to effectively select, develop and scale registry solutions
- Broad stakeholder development to underpin effective UX design and ensure stable change management processes
- How to develop and adopt business intelligence measures to accurately measure registry health and value-add

Purpose and Acknowledgments

While each registry must tailor its approach to the unique needs of its stakeholders, a fundamental principle that emerged at the summit is that adopting unified and collaborative processes and standards (and continuing to assess these over time) is essential for making well-informed decisions about public health policies, especially in advancing our understanding and management of Parkinson's disease.

It is our hope that the findings from these two summits, when combined with model legislation, will enable future registry efforts to begin with a head start, enabling the ability to build on previous work to more easily determine what data to collect, how to collect it and how to more easily and effectively legislate and operate Parkinson's disease registries which contribute to shared goals of treating and ultimately curing Parkinson's disease. As there is not currently a national Parkinson's disease registry, continuing to support statewide efforts will be crucial for effectively understanding the diverse and heterogeneous origins, symptoms and progression of Parkinson's disease as we seek to provide resources to those impacted.[i]

The authors extend our sincere gratitude to all participants of the 2023 Parkinson's Disease Registry Technology Summit. Special thanks to the planning committee, an assembly of esteemed experts in data science, health informatics and neurology, who provided invaluable insights and guidance. We are especially thankful to the advocacy organizations, federal agency representatives and the dedicated MJFF staff whose collaboration underpins the advancement of Parkinson's disease research. The summit's success is a testament to the collective effort and commitment of all involved, and we are confident that the outcomes will significantly contribute to the progression of Parkinson's disease registries.

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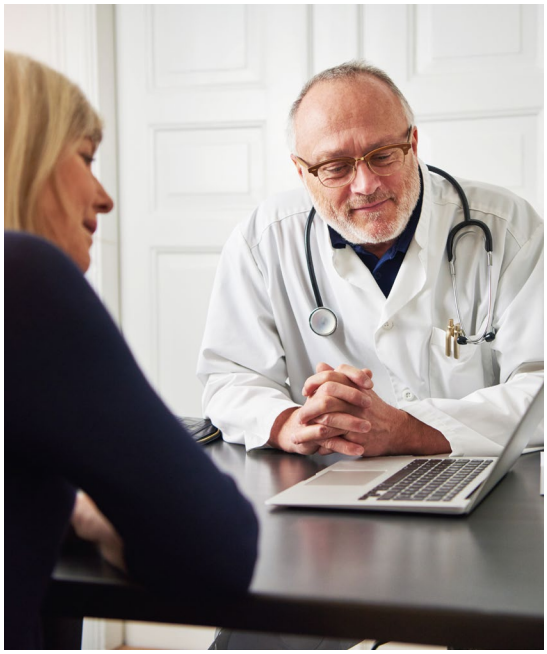
Acronyms

AAN	American Academy of Neurology
AHIMA	American Health Information Management Association
AI	Artificial Intelligence
APHL	Association of Public Health Laboratories
ASCO	American Society of Clinical Oncology
CDC	Centers for Disease Control and Prevention
CDPH	California Department of Public Health
CSF	Common Security Framework
CSTE	Council of State and Territorial Epidemiologists
DEA	Data Exchange Agreements
eCR	Electronic Case Reporting
eICR	Electronic Initial Case Reports
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
HIPAA	Health Insurance Portability and Accountability Act
HIN	Health Information Network
HITRUST	Health Information Trust Alliance
HL7	Health Level Seven International
ISO	International Organization for Standardization
IT	Information technology
KPI	Key Performance Indicator
LOINC	Logical Observation Identifiers Names and Codes
MIPS	Merit-based Incentive Payment System
MJFF	The Michael J. Fox Foundation for Parkinson's Research
NIH	National Institutes of Health
NLM	The National Library of Medicine
PD	Parkinson's disease
PGHD	Patient-generated Health Data
PHA	Public health authority
PHI	Protected Health Information
RXNorm	Medical Prescription Normalized
SNOMED	Systematized Nomenclature of Medicine
TEFCA	The Trusted Exchange Framework and Common Agreement
USCDI	United States Core Data for Interoperability

Executive Summary



As more states establish registries to understand the incidence and prevalence of Parkinson's disease (PD) there is a growing need to create resources to aid in those complex undertakings. To that end, the goal of the 2023 Parkinson's Disease Registry Technology Summit was to provide registry operators with an overview of issues impacting registry technology design and to equip them with the confidence that they have considered the right questions before making design decisions.

This report seeks to inform strategies guiding technological development of registries by covering a range of topics, including interoperability, data governance, stakeholder engagement and electronic health records, among others. A registry must be adaptable and engage a broad array of stakeholders who regularly provide feedback. Technologies, standards and use cases will change, but the goal of helping those impacted by PD will not.

As such, attendees recommend that:

Implementing Bodies

+ Develop guidelines for integrating patient-generated health data (PGHD) into registries, prioritizing patient centricity and enhancing data comprehensiveness.

+ Establish clear standards for "minimum necessary" data in public health registries to ensure HIPAA compliance and reduce administrative burdens.

+ Define KPIs and principles for assessing registry health at each maturity stage, regularly reassessing throughout the design process and leveraging existing standards for guidance.

Registry Operators

+ Form advisory committees with diverse stakeholders for sustained engagement and trust-building.

+ Implement a varied funding strategy for long-term sustainability.

+ Offer clear, accessible fact sheets and updates for care providers and advocates, outlining registry importance and usage.

+ Develop a communication plan to address registry data limitations, empowering stakeholders to advocate for the PD community and prevent misuse through transparency.

Stakeholders & Advocates

+ MJFF update legislation for PD registries to receive eICR automatically, aiding scalability with public health support.

+ CDC or CSTE lead a national steering committee on tech standards like FHIR, fostering consensus.

+ CDC or CSTE establish a coalition of registries, sharing best practices and emphasizing case reporting value.

+ All stakeholders develop advocacy plans and resources for funding, legislation, and scaling.

+ All stakeholders create a "responsible PD registry framework," addressing equity and privacy with recurring feedback.

This report, when combined with the previously developed model legislation and maturity model, can form a solid foundation upon which future registry efforts can build. Further, the recommendations aim to inspire stakeholders to address our shared goal of improving health outcomes for those impacted by PD.

Why Registries, Why Now and What's Stopping Us?

Given the heterogeneity of its presentation and the relative complexity of diagnosis, our understanding of the epidemiology of PD leaves much to be desired.[ii] It is our hope that developing state-level PD registries will enable us to build a clearer picture as we work to refine research goals, assess interventions and outcomes, and drive development of novel treatment options and better public health outreach. This understanding is hampered by the considerable access to care challenges which impact our understanding of incidence and prevalence and therefore the full nature of the disease.[iii]

To better allocate resources, evaluate treatment efficacy and uncover and remediate inequities in care, we need to have a better picture of who has PD and where, rather than our current visibility based on who has PD and has seen a neurologist. Given the decentralized nature of U.S. health care data, building more comprehensive state registries will enable more effective and equitable public health interventions. It is our hope that demonstrating the utility of registries will galvanize more stakeholders to join in these efforts.

Since our last summit in 2022, states have continued to pass legislation and establish population-based registries to address the burden of PD, with the number of registries growing from six to 10. In addition to unprecedented engagement at the statewide level, scientific advancements make it imperative to push ahead now. Further, a new test allowing researchers to detect alpha-synuclein pathology in the spinal fluid of individuals with PD has opened the door to a way of defining disease that is based on underlying biological processes (vs. clinical symptoms) that may be a game-changer for epidemiological research. A biological definition expands population registry opportunities to include those who have not yet received a diagnosis or manifested clinical symptoms but may be at elevated risk. This, combined with a newly proposed biological staging system (the Neuronal Synuclein Disease Integrated Staging System or NSD-ISS), are exciting new advances which make this work ever timelier.[iv]

Despite ongoing momentum and recent developments, the road ahead for registries is not without challenges. Central among them is the need to identify sustainable processes and structures for data collection and use. As the amount of available data expands, it will become increasingly complex to parse and leverage at scale, so implementing states need technological tools and frameworks to aid in addressing this problem.[v] Health data such as those collected by registries are a minefield of ambiguity in data collection and management standards.[vi] Finally, registries must grapple with how to represent the diversity of those impacted by PD to provide equitable care.[vii]

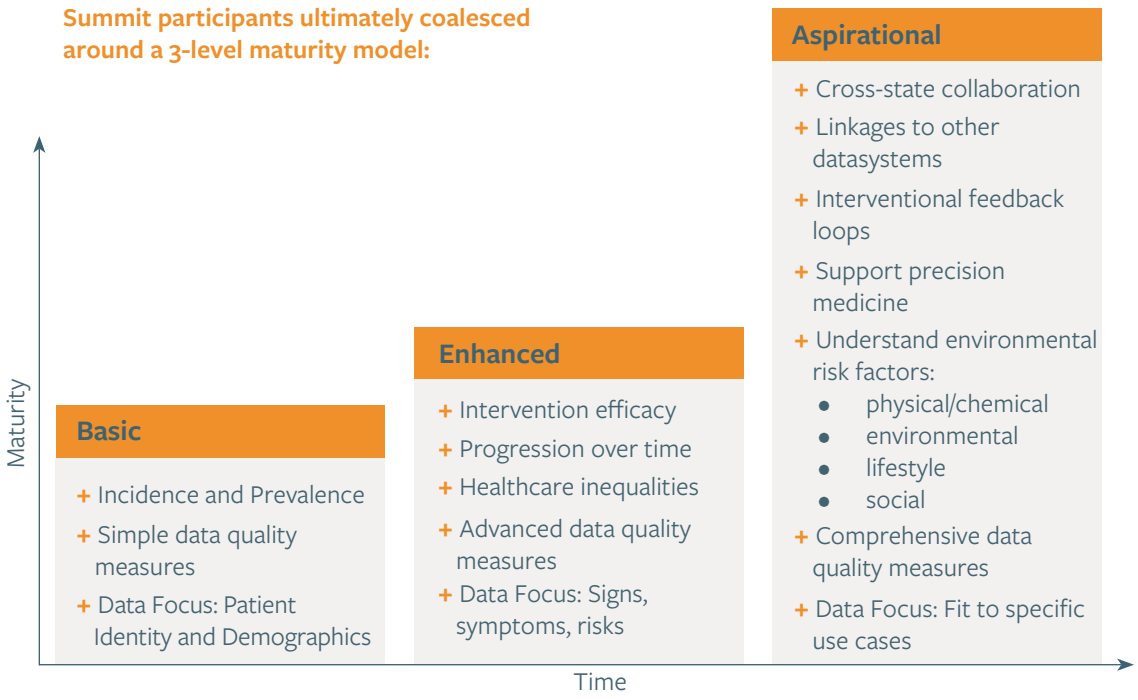
The following report provides analysis, discussion and recommendations regarding the effective deployment and utility of technology in support of PD registries.

2022 Data Summit Review

This report builds on the results of the 2022 Data Summit report, Consensus-Based Recommendations for Establishing Statewide Parkinson's Disease Registries, which centered on building consensus around the common data elements that should be included in such registries in accordance with their level of maturity to meet an array of public health needs and research goals. The purpose of the 2022 Parkinson's Registries Data Summit was to build consensus around a maturity model for registries' data collection among Parkinson's disease researchers, registry operators and other stakeholders. The Consensus-Based Recommendations for Establishing Statewide Parkinson's Disease Registries from the 2022 summit and resultant recommendations can be found here.

The 2022 summit resulted in the development of a three-tiered model, providing for basic, enhanced and aspirational levels of development. Each level is based on the functionality expected as registries grow to serve shifting stakeholder interests. To more accurately determine incidence and prevalence and to service other policy and research goals, it was critical to align around a common understanding of the specific data components that should be collected.

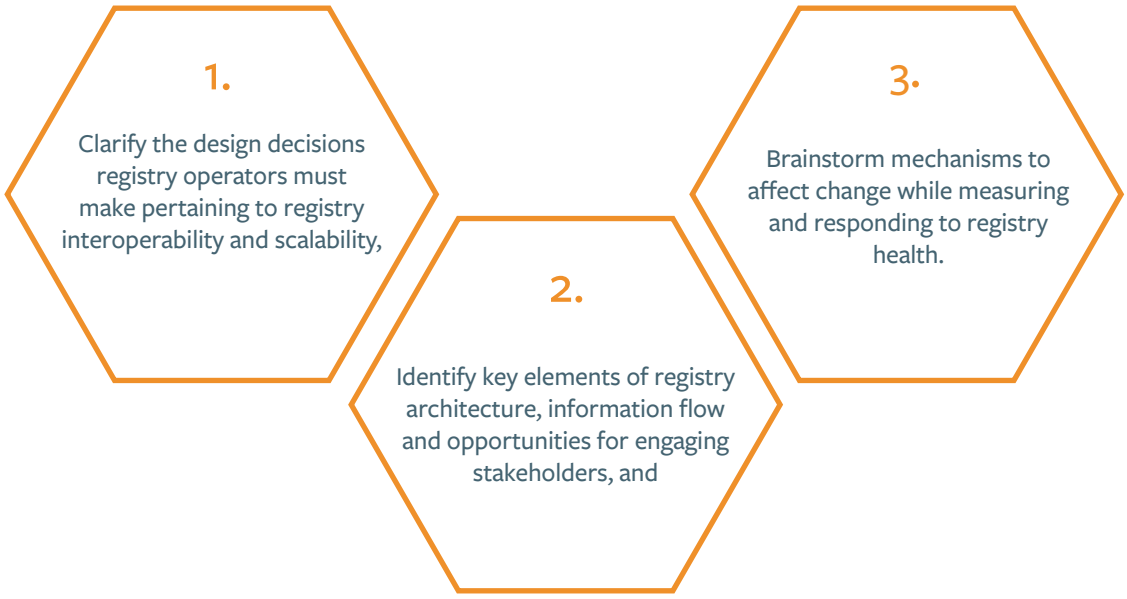
Summit participants ultimately coalesced around a 3-level maturity model:



The fact that there is no simple electronic health record (EHR) standard for identifying all possible occurrences of PD is foundational to this challenge. To capture the breadth of those impacted by the disease, participants proposed automating data extraction, aligned around adopting a broad definition of PD to be continually reviewed by an advisory council, and to remain flexible as our understanding of PD evolves. Automation, flexibility and ongoing self-review of operations remained themes in our 2023 summit.

Objectives of the 2023 Technology Summit

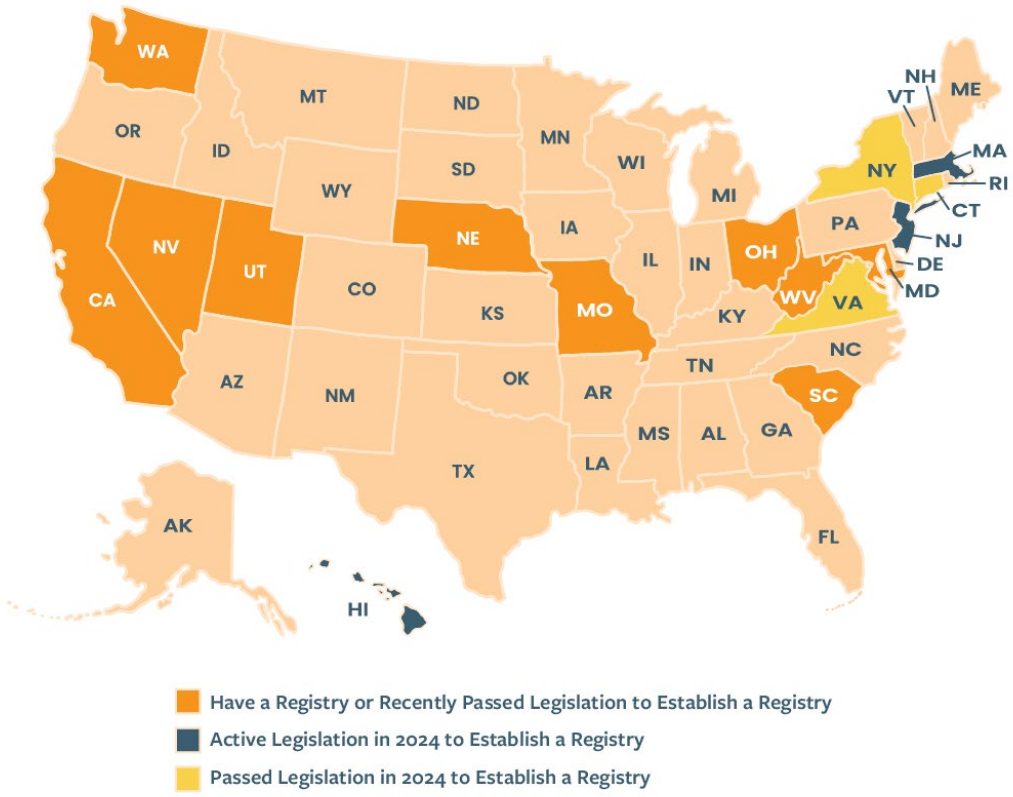
The 2023 summit aimed to build on the previously developed maturity model and model legislation. Specifically, through moderated panels, interactive sessions and expert presentations, this summit sought to:



The summit did not seek to provide recommendations on specific technology products but rather identify potential risks and mitigation plans for shared challenges. Summit participants sought to lay the groundwork for future registry operators to better plan for stakeholder needs from launch. The discussions in this report are intended to help registry operators better understand key decision points for maximizing interoperability and scalability, as well as quantify and analyze registry performance for ongoing maintenance, storytelling and the enablement of improved treatment and care. Taken together with the 2022 Summit report, this report is intended to empower registry operators to assess state-specific needs not only to engage with these shared goals, but also to have a head start in effectively capturing, managing and using registry data.

State of the States

Through legislative action, an increasing number of states are creating their own Parkinson's disease registries. The status of adoption is illustrated in the following diagram:



At the beginning of 2023, there were six known PD registries in the United States: Nebraska (1996), Washington (2007), Utah (2015), California (2017), South Carolina (2022) and West Virginia (2022). Washington operates a voluntary repository, which 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 2023, MJFF led efforts to pass statewide registry legislation in four additional states: Maryland[viii], Missouri[ix,x], Nevada[xi] and Ohio[xii]. MJFF also successfully advocated for additional state funding for the longstanding registry in Nebraska, which will modernize the infrastructure and allow for electronic submission of patient data. In 2024, there was active legislation in Connecticut, Hawaii, Massachusetts, New Jersey, New York and Virginia.

In 2022, Massachusetts established an Advisory Committee to the Massachusetts Department of Public Health for the development, implementation and collection of information necessary to determine the incidence and prevalence of PD in the Commonwealth. In May 2022, the Committee released a final report that made various recommendations to establish a PD registry. At the time of this writing, the bill that would implement those recommendations remains under consideration by the Legislature.

As of June 2024, Connecticut, New York and Virginia have passed legislation to establish registries to collect PD patient health information. Upon being signed into law, this would bring the total number of states that have taken action to establish PD registries to 13, up from just four states at the beginning of 2022.

Case Studies: California and South Carolina Registries

To illustrate variations in approaches to the creation of PD registries, the summit included a panel discussion with administrators from registries in California and South Carolina. These administrators highlighted the importance of adherence to standards regimes pertaining to legislation, technologies and data. While emphasizing excitement for registry expansion and broadening public health impact, they also noted shared challenges pertaining to funding, staffing and shifting legal, political and data requirements.

California

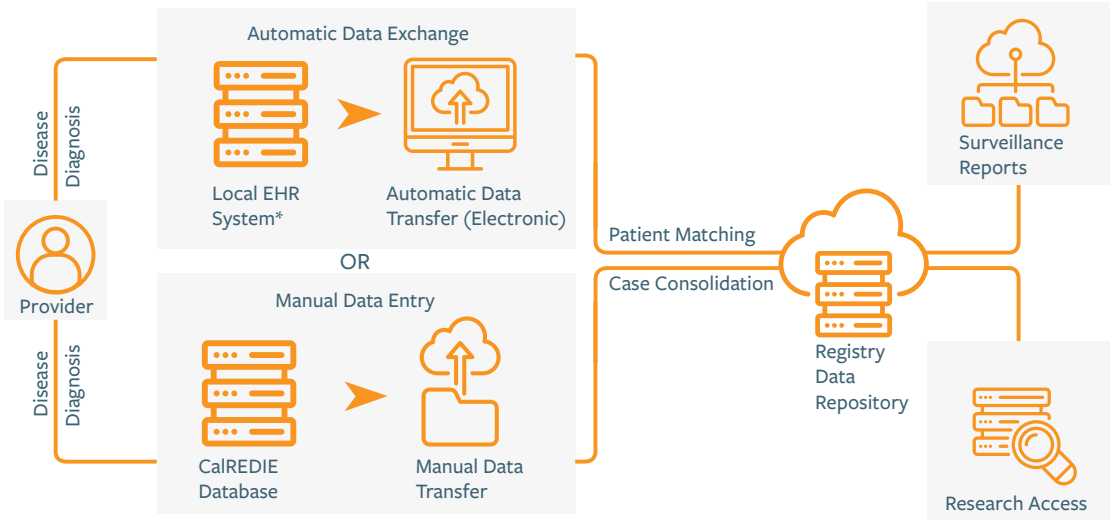
In 2017, legislation mandating the creation of a pilot PD registry was passed in California. This is the largest population-wide state registry, with a primary focus on epidemiology, and requiring mandated reporting of all encounters with new diagnoses of PD or changes in PD management, regardless of specialty across the state. This initial mandate required registry program renewal, which ultimately led to the broadening of the program to include a neurodegenerative disease registry and removed the sunset date.[xiii]

California's PD and neurodegenerative disease registries, which are funded via legislative budget through the California Department of Public Health (CDPH), allows for two ways of collecting data: One option is for automated data collection through EHRs and the other for manual database entry. These two data sources are then aggregated, and data quality checks are performed.

These two methods were deployed based on the California Department of Public Health's experience with the California cancer registry. The system primarily relies on automatic case reporting — more than 88 percent of total records are collected this way — but to reach as many providers as possible, the manual entry option was created for use by clinicians who were either unable utilize the automated workflow or not served by electronic health systems.[xiv] There are trade-offs in data quality and record completeness from the two approaches. On the one hand, the rates of duplicates were higher from automated sources than from direct entry; on the other, manual entry generally results in more complete data records.

While the California registry includes a legislative mandate for physicians to report PD cases, there are no established consequences for failure to report. Rather than seeking to punish providers

California Neurodegenerative Disease Registry



*Local Electronic Health Records System

who fail to report, CDPH instead seeks to partner with providers to encourage reporting. Administrators have focused on keeping data collection as basic as possible to enable compliance with reporting requirements, including potential use of SNOMED standards.[xv] To simplify reporting further, the registry relies on a provider's EHR system to generate an electronic initial case report (eICR). ElCRs are used for communicating disease incidence to relevant public health authorities (PHAs) based on nationally consistent trigger codes embedded within the EHR.[xvi]

South Carolina

In 2022, the South Carolina Legislature passed a bill to establish its own PD registry. In turn, funding to the Medical University of South Carolina for implementation came with its telehealth funding.[xvii] Following this, an advisory committee (as mandated by the legislation) comprising people living with Parkinson's, researchers from state research universities, non-profit partners and clinicians was formed to assist in registry development and implementation. The committee plans to hold an annual stakeholder meeting to provide relevant updates and discuss administrative challenges.[xviii] Representatives from the South Carolina registry strongly recommended the advisory committee model as having provided significant benefits to inform registry technical decisions. The hope is that, in addition to its epidemiological focus, an effective registry can help to close gaps in clinical care by connecting identified cases with public health services.

In South Carolina, providers are required by law to report every incidence of PD, though patients can choose to opt out of providing the registry with additional data. As multiple statewide PD registries had been established by 2022, administrators believed there was an adaptable framework available to utilize in the creation of the registry and administrators have looked to existing health care registries in the state for guidance. Their Alzheimer's disease registry, which was established in 1988, stores its data in one central location, pulling data from multiple sources such as insurance claims, emergency room visits and mental health rehabilitation clinics.[xix] Administrators acknowledge that successful integration of multisource datasets requires a great deal of personnel and a plan to maximize the involvement of graduate and postdoctoral students at state universities as a means of addressing limited staff hours.

A major consideration for the South Carolina Registry Advisory Committee (and for other registry operators or advisory committees) has been to identify future funding sources for the registry. They strongly advocated for state-provided funding to be continuously allocated to the registry and believe that associated costs were expected to decrease in subsequent years following the initial implementation.

Interoperability, Integration, Standards and Risks in Leveraging Electronic Case Reports

As statewide registries centralize and harmonize data from many reporting entities to paint a complete picture of a patient's health, ensuring maximal interoperability and integration between these systems is critical for both short- and long-term success. This applies to the systems and infrastructure underpinning registries, as well as the standards used to govern the data itself. Ensuring that registry systems are built to pursue outcomes, rather than specific solutions, will enable them to grow and adapt alongside standards and use cases.

For population-wide registries, leveraging the electronic Case Reporting (eCR) standard is worth considering, especially for public health surveillance and action purposes. eCR is the automated generation and transmission of case reports from EHRs to public health agencies for review and action.[xx] The reports under these systems are referred to as electronic initial case reports (eICR). Support of eICR functionality is a requirement for certification of EHR's; use of eICR functionality is a component of the CMS Promoting Interoperability incentive payment program. The California Parkinson's Disease Registry included the eCR specification to encourage adoption as a key method of automated reporting.

Each eICR report may be triggered by discrete information in the EHR, including visit types, a trigger diagnosis code (i.e., ICD-10 code from a visit to a provider); lab order (LOINC)[1]; lab result (SNOMED, LOINC)[2]; or prescribed medication (RxNorm).[3,xxi] Reports are forwarded to a central AIMS platform (Association of Public Health Laboratories Informatics Messaging Services) which forwards each report to the appropriate state, county, territory and/or public health agencies based on specific reporting requirements. Importantly, the AIMS platform is capable of sending a response back to the reporting entity.

In general, while support and use of EHR's to transmit eCR reports is now more widely adopted for reportable communicable disease conditions, particularly after the COVID-19 pandemic, use for chronic conditions such as PD remains relatively sparse. Further, support for receiving the eCR reports electronically by the various public health agencies remains varied. Manual reporting workflows usually remain as long as one receiving agency has not yet developed the infrastructure to receive eCR, slowing overall eCR adoption. In addition, it is important to note that direct electronic reporting via eCR needs domain-specific definitions for future evolution as it applies to chronic diseases in general and neurologic diseases specifically to develop eCR for reporting beyond the minimal case definition (see discussion of USCDI+ below, as a possible opportunity for this). Parkinson's disease was added as a reportable condition in June 2019, using trigger codes determined by the Council of State and Territorial Epidemiologists with input from Centers for Disease Control and Prevention and the Association of Public Health Laboratories. As of October 2023, more than 30 states (with another five and Washington, D.C. in testing) are processing eICR into surveillance systems. However, only a small fraction of PHAs (California, Maine, Nebraska, Utah, the Southern Nevada Health District and the Turtle Mountain Band of Chippewa Indians) are receiving eICR pertaining to PD.[xxii] Meanwhile, while Nebraska's PHA is receiving eICR pertaining to PD, they are still working to integrate them into their registry.

[1] Logical Observation Identifiers Names and Codes are a set of identifiers, names, and codes for clinical and laboratory observations, health care screening/survey instruments, and document type identifiers.

[2] SNOMED CT is one of a suite of designated standards for use in U.S. Federal Government systems for the electronic exchange of clinical health information and is also a required standard in interoperability specifications of the U.S. Healthcare Information Technology Standards Panel.

[3] RXNorm is a naming system for drugs and a tool for supporting interoperation between drug terminologies and pharmacy knowledge base systems produced by The National Library of Medicine (NLM).

While the eCR is one Health Level 7 (HL7) standard that can support public health surveillance and action, there are other standards that bear monitoring, consideration, or implementation when setting up registry infrastructure. These include:

- Fast Healthcare Interoperability Resources (FHIR), a Health Level 7 (HL7) global standard for management and exchange of health data which provides a framework and protocol for how health care data is structured and shared among systems.[xxiii] A specific FHIR standard for PD reporting has not been established. An implementation of eCR via FHIR is available.
- United States Core Data for Interoperability (USCDI), a standardized set of health data classes and data elements, updated annually, and represents core requirements that certified EHR's must support.[xxiv] A framework called USCDI+ will include domain-specific and public health remains under development.[xxv]
- The Trusted Exchange Framework and Common Agreement (TEFCA), which are a common set of principles and a contractual agreement designed to promote trust and enable secure information sharing between U.S.-based qualified health information networks (QHINs).[xxvi] The TEFCA standard is intended to become an interoperability floor for national health exchange with first QHINs going live in 2023-24. Public health use cases for TEFCA are a priority on the roadmap and have not yet been developed as of this meeting.

They also considered ongoing risks across three domains, complicating efforts to improve registry interoperability, including:

Political Barriers

- Registries can be impacted by political climate, will and resource limitations. Infectious disease domains are currently prioritized over chronic diseases and government-led surveillance programs face mixed public sentiment.

Data Access Limitations

- PHAs can only access data for reportable conditions within their jurisdiction, which can limit standards development and uptake across jurisdictions.

Provider Data Concerns

- Providers worry about excessive data access by public health entities, and this may influence unconscious biases in reporting.

Despite these challenges, there is enthusiasm around potential aspects or activities for improving registry efficacy and leveraging eCR. These include:

- **eICR utilization:** eICRs may also be suitable for neurological diseases, but there needs to be significantly more widespread adoption by PHAs. For example, while eCR is widely promoted and used appropriately for communicable diseases, established statewide registries for conditions such as cancer largely do not leverage eCR.
- **Chronic health reporting:** There is a need for state public health agencies to familiarize and integrate chronic disease reporting into existing eCR workflows for both receiving, exchanging, and utilizing eCR reports.
- **Community action:** Advocacy is necessary to make Parkinson's a reportable condition to enable access to data. Placing individuals with Parkinson's in advocacy roles to motivate lawmakers and contribute to advisory committees is desirable.
- **Multiple data frameworks:** Integration of federal frameworks and regional Health Information Exchange (HIEs), which enable care providers and patients to access and/or share health information, is encouraged for rapid scalability.[xxvii]
- **Standardization for data quality:** Concept and infrastructure consensus standards remain pending for PD and alignment of health information exchange standards with methods for reportable chronic condition use cases must be aligned or made available for registry development, including eCR, FHIR, existing HIEs, TEFCA, and other eCR formats should be explored.[xxviii] Aligning around best quality assurance practices and a standard format is critical to minimize technological challenges.

Using established frameworks and standards, while monitoring for evolving technologies that show promise, is necessary to develop and improve PD registries. A survey of such infrastructure technologies is critical to building upon the experience and successes of other registries or research efforts. By building consensus around registry standards, we can take some of the guesswork out of these efforts through sharing of collective wisdom, which is of particular importance given the cost and resource budgetary restrictions many registries face. Beyond this, data standards will help to minimize bias resulting from uneven selection of data elements or discrepancies in defining or identifying cases while ensuring that key data is not lost if determined to be of lesser interest in one use case versus another. Further, these standards can remove some of the guesswork and anxiety around required adherence with governing standards.

During the summit, participants suggested that ongoing leadership from a neutral convener would be particularly beneficial to align around a standard palatable to PD registries. This role may also require advocacy to existing standards setters on behalf of the neuronal synucleinopathy community, to ensure that the models effectively used in infectious disease and cancer are able to support data needs for chronic degenerative neurological conditions. Participants suggested CSTE or CDC would be strong candidates to lead efforts and convenings on these topics. Partnerships with evolving public health standards such as TEFCA or third parties with experience in the large-scale registry development or interoperability space may be considered.

Updating model legislation to ensure that eICRs can (and are required to) be accepted by PHAs for use in supporting statewide registry efforts will go a long way in clarifying our picture of who has PD and where. Ultimately, scaling registries underpinned by eCR will require considerable buy-in and alignment across public health agencies, health IT and EHR industry partners, and health care organizations.[xxix]

Stakeholder Perspectives for Registry Workflow

Statewide PD registries should accommodate and serve as many stakeholder groups as possible. By exploring the various components and use cases of a statewide registry, summit attendees worked to outline considerations for system architects to bear in mind when working towards this goal. Participants recognized that while each registry has a uniquely defined purpose and focus, they will generally share the same types of stakeholders, who may bring contradictory priorities to the design process. By considering how these categories of stakeholders might interact with a state PD registry, their perspectives can highlight opportunities to streamline the flow of information and gain buy-in. Further, by understanding the potential and limitations of each stakeholder's ability to contribute to the usefulness and completeness of registry data, we can develop a registry that produces more accurate and actionable data.

Summit attendees explored potential interaction points and priority workflows for registries from the following perspectives:

Designing Parkinson's Disease Registries

As a Clinic

Streamlining clinic operations by assigning specific staff to data reporting, utilizing informatics for efficient data extraction, standardizing documentation, and automating EHR reporting, while emphasizing quality through feedback mechanisms and addressing diagnostic errors and operational challenges.

As a Researcher

Driving research through data extraction and analysis, emphasizing data integrity and the need for interoperable standards, while navigating the challenges of standard creation, legal permissions, and the complexities of multi-state studies.

As an Advocacy Organization

Advocating for patient interests by emphasizing research questions, ensuring data security and clarity in protocols, addressing risks of misinterpretation, facilitating database interconnectivity, and shaping registry policies for better public accessibility and perception.

As a Patient

Empowering patients through education and choice in data sharing, enhancing healthcare integration and privacy, while addressing data quality and misclassification risks in patient-generated health data contributions.

As a Doctor

Enhancing clinical workflows by integrating registry reporting with EHRs, automating patient identification, ensuring data quality and accuracy through feedback mechanisms, audits, and efficient EHR usage, while balancing clinical responsibilities with data reporting demands.

As a Public Health Body

Coordinating population-level data management by engaging stakeholders, ensuring data quality and deduplication, setting standards and guidelines for collection, leveraging existing pathways, and balancing the need for autonomy with the imperative for standardization.

As a State

Defining key data elements, securing funding, and establishing interoperability standards to align data reporting with public health needs, focusing on integration standards like USCDI+, and managing data security and interpretation risks at the state level.

The following stakeholder-centric workflow models are intended to help individual registries in identifying potentially fruitful routes for interoperability (and their purpose), based on the registries' unique requirements and goals. These routes may include points of interaction with other systems, organizations or data sources. In addition, these models can be used to clarify key design questions to align with real-world needs and challenges. Ultimately, it is our hope that stakeholders can leverage the real-world evidence that registries generate to provide crucial guidance that impacts clinical decision-making in research and patient care; providing information on the actual effectiveness of treatment regimens, drugs, and devices.

Designers can use this information to anticipate challenges to stakeholder collaboration, setting the groundwork for a comprehensive, sustainable and dynamic registry. These workflows can also inform electronic health record vendors and health information exchange standard setting organizations to add to their roadmaps for development and implementation.

Patient-Centric Workflow:

The Epicenter of Data and Care

Participants representing patient-centric workflows emphasized the importance of educating newly diagnosed patients about the registry, its public health utility and the limitations on data use while providing them with the choice to participate or opt-out. Some enhanced and aspirational data uses would require information that can only be obtained directly from patients. Enabling patients to contribute additional information via a portal managed by registry operators would require an integration between personal health records and broader health care systems (as well as user access controls, including data use agreements) but could boost trust. Registries wishing to incorporate patient-generated health data (PGHD) may find considerable benefit from doing so (i.e., more complete records), but patients are likely to request frictionless and low-effort contribution methods, which can raise considerable privacy and data quality concerns. Workshop participants also specifically noted that, in the context of PD's current status as a clinically defined disease, misclassification risk may be particularly high for PGHD workflows.

Provider-Centric Workflows:

Bridging Clinical Care and Data Reporting

Participants representing provider-focused workflows focused on integrating the registry's reporting processes into existing clinical practices. They ranged from automated identification of PD via EHRs to creating more manual feedback mechanisms (such as a provider portal for data entry) to ensure data quality and completeness. Regular audits of health records and training on proper coding are recommended. Summit participants emphasized the importance of dynamic updates to PD diagnoses and the facilitation of seamless data reporting which minimized instances of duplicate records. Ensuring accurate data capture within EHR systems and facilitating seamless data transfer to the registry presented major interoperability challenges. Concerns about diagnosis accuracy and data coding surfaced, alongside questions about leveraging EHR features for efficient data entry and retrieval. Beyond this, there are health equity concerns associated with eCR, as that data can only reach populations with a formal diagnosis or who have access to a provider who would be generating EHRs. That said, awareness, feedback and appreciation for participating in reporting requirements, even when automated, would help build trust in the evolving era of increasing registry reporting. Leveraging EHR clinical decision support capabilities and the public health or registry feedback with action items, including enhanced access to neurology or PD expertise or relevant community resources could help providers better care for their patients, furthering the value provided by registries. This workflow and interoperability considerations spotlighted the intricate balance between clinical responsibilities and the demands of data reporting.

Clinic-Centric Workflow:

Operationalizing Reporting and Data Analysis

Participants representing clinic-focused workflows addressed practical aspects of data reporting at the clinic level. It involved identifying staff responsible for reporting, utilizing informatics tools

for efficient data extraction and ensuring the use of standardized note elements. The participants discussed the need for feedback mechanisms to compare data quality across practices. This workflow focused on automating data reporting via EHR systems, underscoring the need for standard data elements and streamlined processes. Participants representing the clinics recognized the risks of diagnostic errors and the burden of integrating new reporting processes.[xxx] Questions about the optimization of EHR for reporting and the potential for feedback loops to improve data quality were central to the discussion, reflecting the operational challenges in data management at the clinic level.

Public Health Body-Centric Workflow:
Coordinating Data Collection and Utilization

Participants representing public health body workflows focused on managing the data from a broader public health perspective, involving stakeholder engagement, data consolidation and quality assurance. The discussions highlighted the need for deduplication and ensuring that each patient's data was accurately represented in the registry. Here, participants representing public health bodies were tasked with defining data needs, standards and the operational model for data collection and usage. This included working to develop guidelines for the appropriate levels of data collection at each stage of registry maturity. This highlighted the potential of leveraging preexisting collection pathways, such as HIEs and claims data. The questions raised by the participants focused on balancing data collection autonomy with the need for standardization, highlighting the complexity of managing data at a population level.

State-Centric Workflow:
Setting Standards and Ensuring Compliance

Participants representing state workflows included a strong emphasis with that body playing a central role in defining data elements, securing funding and establishing interoperability standards. Critical areas included the integration standards (such as USCDI+, an expansion of USCDI standards aimed at meeting domain or use case-specific needs) and ensuring that data reporting was aligned with public health needs.[xxxi] The risks were predominantly centered around data security and the potential for misinterpretation of data. Questions about informing reporting parties and managing data requests reflected concerns about operationalizing these standards at a state level. Consensus recommendations for how best to leverage the potential for eCR-type public health responses to EHR's, clinics, and provider teams for appropriate public health action should be considered.

Advocacy Organization-Centric Workflow:
Championing Patient Interests and Data Security

Participants representing advocacy organizations focused on identifying research questions and ensuring data security is effectively adopted, understood and communicated. They emphasized linking various databases and ensuring the clarity of data security protocols. The risk of data misinterpretation and storage issues was paramount. Questions about linking patients across databases and making data publicly accessible underscored the importance of advocacy in shaping registry policies and public perception. Advocacy organizations can play a role in pushing for the development of consensus standards to support sustainable interoperable registries that provide value to patients, caregivers, and clinician teams.

Researcher-Centric Workflows:
Extracting Insights and Advancing Knowledge

Participant representing researcher workflows centered on data extraction, analysis, and the pursuit of new research opportunities. The importance of quality control and stakeholder review was emphasized by the participants, ensuring the data's integrity for research purposes. Their workflow underscored the need for interoperable data standards that support phenotyping and predictive analytics. The risks involved in creating standards and the potential for information loss in data transformation were critical concerns. Questions about legal permissions, data structures and multi-state study highlighted the complexities researchers face in leveraging registry data.

This list of possible data workflows and stakeholder priorities for PD registries emphasizes the complexity of the task at hand. It is difficult to balance competing stakeholder needs in making specific technology decisions, such as whether to pursue a potentially costly point of interoperability given one set of stakeholder interests. Advisory boards comprising representatives of stakeholder groups are one possible route for pressure-testing technical design decisions, as demonstrated in South Carolina and in many voluntary registry models. Concerns about data privacy and the perception of surveillance are prominent for many stakeholder groups, underscoring the need for transparent communication, development and delivery of training and/or educational materials to stakeholders. Automation might reduce the administrative burden to support an individual stakeholder's interests but taking the stakeholder ecosystem as a whole might create other data quality concerns. As described in the next section, effective data governance can be a tool to take advantage of the opportunities available from stakeholder-centric workflows without losing focus on registry purpose.

Data Governance for Disease Registries

Establishing a clear data governance plan is critical to the establishment and ongoing utility of registries. Data governance, defined by the American Health Information Management Association (AHIMA) as "the overall administration, through clearly defined procedures and plans, that assures the availability, integrity, security, and usability of the structured and unstructured data available to an organization," is fundamental to the trust required for registries to scale.[xxxii] Transparency pertaining to the people, processes and technology which underpin how the data is collected, handled and used by registries is paramount to maximizing buy-in and building trust, as both technology and oversight risks will be present.

From a process and technology perspective, there are several recurring risks. These include adoption of insufficiently flexible solutions for data capture, lack of fieldwide, uniformly adopted data standards, varying reporting requirements, privacy concerns and concern about legal exposure when handling protected health information (PHI). Failure to invest in sufficiently flexible technology solutions could inherently limit the lifespan and utility of a registry if it is rendered incapable of addressing shifting requirements.

To promote good data governance practices among the people involved, it is recommended that providers maintain preexisting certifications (i.e., HITRUST Common Security Framework)[xxxiii] to comply with relevant regulations (i.e., HIPAA).[xxxiv] Where feasible, leveraging existing electronic medical record (EMR) solutions or preexisting payment structures such as the merit-based incentive payment system designed to enable providers to receive increased payments for services provided to Medicare patients also makes it easier for providers to adopt good data governance practices.[xxxv] To ensure feasibility, it is encouraged to have ongoing conversations with regulatory bodies to understand future mandatory reporting requirements.

Development of educational materials either by registry operators, fieldwide professional societies or non-profit stakeholders can assuage data privacy concerns and reduce communication burden. Creation and sharing of clear policies on how to handle data with data privacy in mind further builds trust and creates safeguards. An example of this, used in both the ASCO and AAN registries, is the implementation of a firewall between those who have access to PHI (either at the registry or provider level) and those who have access to deidentified data. This has the added benefit of protecting stakeholders from legal risk. Downstream, user access controls and use policies must align with patient consents (as applicable), which should be processed digitally whenever possible to reduce the burden on providers, clinic staff and patients. For those patients, provision of an opt-out option for contributing their data to registry efforts was found by the summit participants to be highly favorable for reporting incidence of cancer.[xxxvi]

Workshop participants recommended eight broad data governance policies which all individual PD registries could implement and transparently document to build trust in registry operations:

1. Establish board-appointed oversight committees
2. Publicly share clear compliance policies and procedures
3. Conduct routine data quality assessments to promote alignment with terminology and reporting standards
4. Develop transparent collection and distribution mechanisms
5. Adopt preexisting security standards
6. Institute and enforce legal safeguards
7. Conduct regular security audits
8. Set a cadence for reassessing quality control standards to reflect latest advancements

Data Governance Policies

It is important to consider that equity is a fundamental component of data governance. Workshop participants noted that existing and prospective PD registries are deeply committed to equity and privacy in design, while recognizing that this can be difficult to achieve in practice. Those responsible for developing PD registries would benefit from guidance on achieving equity and privacy goals that focuses on the specific risks related to data collection and use. Ideally, this guidance would provide a framework not only for understanding and mitigating these risks, but also to center equity and privacy concerns in oversight structures and design processes. These are challenging problems, but it is better to start somewhere and improve, rather than to try to retrofit equity and privacy considerations to preexisting structures.

To promote widespread adoption of the eight broad data governance policies recommended by workshop participants, attendees expressed enthusiasm (and the need) for the establishment of a national-level data governance group. They identified a strong need for national-level coordination where registries can collaborate on a regular basis, discuss the path forward, and define a national roadmap. This would be inclusive of registry operations such as data governance, but also IT development, as well as data standards (such as the development of neurologic disease-specific eCR standards). The North American Association of Central Cancer Registries (NAACCR), an umbrella organization for all U.S. and Canadian cancer registries which works to set standards and improve quality of cancer registry data, would be one governing body to consider as a model.[xxxvii]

Even in the best case of strong data collection workflows combined with strong data governance, every registry's data will have limitations. Data limitations are simply a reality and cannot be avoided entirely. As noted above, these limitations may derive from issues of equity in access to care, they may be a function of interoperability decisions, or any number of other sources. Each registry is well-positioned to identify known limitations stemming from technological and data design decisions. Being transparent with stakeholders about these limitations can help avoid data misuse and build trust in the technological architecture of the registry over time.

Technology Infrastructure: Systems and Security Requirements

Understanding the technology required to operate a registry is critical to create a system which meets stakeholder needs and use cases. Shifting interests, limited resources, lack of national standards and the desire to build flexible, scalable and equitable solutions clearly demonstrates the complexity of the work at hand. The following considers critical aspects of registry infrastructure.

First, a registry must have secure network infrastructure. Given the highly sensitive nature of the data and the potential trust gap this creates, sufficient network and firewall policies must be implemented, bearing in mind both intrastate variability between health systems as well varying legal regimes across states. Implementing a commonly used cloud architecture could minimize some interoperability concerns but increasing system security could come at the cost of excluding some users due to technological knowledge gaps. To supplement security measures, registries must also implement disaster recovery and backup plans in case of data loss or breach. Leveraging best practices such as the backup 3-2-1 rule[xxxviii] or maintaining a security certificate such as ISO27001 (a widely used, international standard for information security, cyber security, and privacy protection)[xxxix] or HITRUST CSF (which covers ISO 27001 standards, along with several others) is recommended, as these practices provide coverage against both financial and operational risks related to data management.[xl] Beyond leveraging these best practices and maintaining a security certificate, one standard that might be considered is the National Institute of Standards and Technology's cybersecurity framework.[xli] This standard is required for federal entities but may be used voluntarily by others looking to reduce cybersecurity risks.

Second, state registries should implement clear authentication and access controls. Balancing the need to protect patient privacy with the desire to maximize data use will likely require the establishment of a multi-tiered approach whereby the mechanisms for providing data to patients or for research application require different access controls. Registry operators would also need to create sufficient internal access controls. Solutions discussed at the summit included two-factor authentication to reduce risk of data breaches as well as public-facing dashboards that enabled limited analysis (but would not make available potentially sensitive data). For inter-registry exchanges, data exchange agreements (DEAs) should be required. The North American Association of Central Cancer Registries, which helps set standards for cancer registries, goes a step further and makes these DEAs available to the public.[xlii]

There must also be measures safeguarding the data itself. To build trust and maintain data privacy and security, registry operators should share and develop materials to enable clear communications pertaining to data privacy and security. When determining data privacy and security standards, registries would benefit from adopting preexisting standards such as those published by the U.S. Department of Health and Human Services (i.e., HIPAA).[xliii] While registries may not be required to comply with HIPAA given their status as public health bodies, HIPAA will likely apply to virtually all registry data contributors, and reliance on this security framework provides assurance of a compatible security and privacy stance.

For instance, TEFCA requires all participating health information exchanges to abide by HIPAA guidance whether they are directly required or not. For registries to maximally benefit from voluntary compliance with HIPAA, it would be beneficial for registry operators to provide clear guidance on what constitutes the "minimum necessary" data to achieve their goals and to make compliance as minimally burdensome as possible for data contributors.

To support the mission and requirements of registries, infrastructure to enable data analytics and reporting for an array of user types should also be developed by operators. Infrastructure would ideally scale over time as the registry matures and use cases expand alongside collection of data. Public-facing tools create an opportunity to give providers value-add in exchange for their participation and contribute to greater stakeholder trust by demonstrating how their participation supports public health goals.[xliv]

Establishing reproducible analytics, clear data provenance guidelines, trusted tools and guidance on how (if not a platform for) users of registry data to engage will increase the likelihood that the information collected is actively used in helping the interests of Parkinson's disease research. Self-service tools, such as a data workbench or data explorer[xlv], may be desirable both for researchers and for internal stakeholders seeking to better communicate around Parkinson's disease and turn transactions into milestones.

Engaging Stakeholders for Long-Term Registry Success

To initiate the design phase of registry development, it is crucial to establish first what the intentions of the registry are. What should this registry achieve, who are the users and what are the use cases? The intentions outline the need to map stakeholder engagement, user experience and change management strategies to appropriately plan the registry development process and ensure that the technologies deployed in support of these efforts are sensitive to present and future requirements, as registries progress across the basic, enhanced and aspirational levels of maturity.

Early involvement of stakeholders and understanding patient and family perspectives is essential. Stakeholder engagement is a multi-faceted process that requires building social, legal and technical trust among a variety of actors with differing levels of expertise, engagement and data use cases. By involving a broad coalition of interested parties throughout the process — and critically, at the outset — registry operators can more effectively build and sustain trust-based operations by nurturing a shared sense of ownership. Beyond this, building a coalition of registries that can exchange best practices and set standards beyond the statewide level can amplify successes by promoting good ideas and ensuring that the responsibility for the creation and of maintenance of shared resources is not a burden to be borne by any one entity. Effective stakeholder engagement can also lead to a reduction of wheel recreation as new registries emerge or preexisting ones mature and require new or additional support.

To effectively engage stakeholders, the transparent development of clear roadmaps and consistent messaging is necessary to maintain trust and manage expectations in a manner that enables a registry to focus on its key mission of benefitting constituents.

Creating and sharing communication plans that outline talking points from an array of stakeholder perspectives can help clarify registry purpose and limitations, decreasing opportunity for misuse of data or damaging of trust. One resource that has proven helpful to this end is easily understandable fact sheets. Developing, publishing and publicizing information about registry operations is an actionable, replicable and—in the case of California's PD registry—a currently employed method that can further solidify trust by demonstrating downstream outcomes and future plans. Additionally, stakeholders can support coalition-building and collaboration development, which may reduce costs and improve efficiencies through sharing resources.

During the registry design phases, it is necessary to identify funding sources to aid sustainability planning. There is a clear need for early registries to focus on achievable goals given known budget constraints and the pressure to prioritize state-mandated initiatives over voluntary ones. Funding greatly impacts the scope and scale of the registry design. As such, any initial technology design and corresponding financial cost should consider not only how much is required to stand up a registry, but also how much would be required to maintain the system or extend to advanced levels of data maturity. Because of this, it is critical for registry operators and state legislatures to think about funding sources that can ensure that a registry has sufficient financial runway for demonstrating success and attracting additional investment. These sources might include state appropriations, federal funding, private funding (i.e., from a foundation), support from medical associations or funding from a university system. Downstream, ensuring that registry advisory boards have data literacy training can help support cost recovery for data requests by identifying when this is feasible, and in determining whether the request itself serves public health interests. Effectively measuring the value that registries provide can help with case-making for obtaining sustained funding and can also demonstrate the opportunity to provide additional value by using the same registry infrastructure to track conditions beyond PD (as is, for example, the case with Virginia and South Carolina's registries tracking Alzheimer's disease and related dementia).

Data consistency is important to the health and success of a registry but must be balanced with a recognition of the fact that needs, standards, stakeholders and interests will inevitably change over time and potentially stray from initial registry use cases. It is critical to set reasonable expectations with stakeholders and ensure they know that developing a registry is a journey. Doing so will enable operators to maintain the confidence of stakeholders so that when the community-developed roadmap invariably deviates from its expected course, it can be positioned as an opportunity for continual improvement rather than a blow to the value proposition of such efforts writ large. Employing established change management tools and techniques is of potential value, but at a more fundamental level, it is critical to leverage regularly occurring venues for open dialogue to remain sensitive to stakeholder needs and sentiment over the duration of a registry's lifespan.

Finally, any engagement or coordination amongst registries at the federal (or even regional) level is complicated by varying data collection standards and distribution regulations. The relationship between federal initiatives and state-level actions is complex, especially given the resource constraints that states face. This is exacerbated by the lack of federal mandate for electronic case reporting.

Business Intelligence for Measuring Registry Health

A healthy Parkinson's disease registry is characterized not just by the data it holds but by its dynamic engagement with the community, adherence to high standards of data quality and security and its ability to adapt to the evolving landscape of research and care in PD. Effective measurement and monitoring of these aspects are vital for a registry's success, in guiding policy decisions, addressing equity concerns and improving patient outcomes driven by the data they collect. Using data to quantify and measure (in as close to real time as possible) registry performance is critical to demonstrating their ongoing value. Just as it is important for registry infrastructure and legislation to be adaptable, how we measure its performance also requires flexibility. As a registry scales, its use cases develop and its data collection efforts mature, the KPIs used to understand its performance must also shift to meet new needs.

To center how registry performance is measured, it is useful for operators to remember that a healthy PD registry can and should be a vital resource for the community it serves. A community-centric approach will ensure that the registry resonates with and represents diverse groups, particularly the underserved and those disproportionately burdened by PD. This approach advocates for inclusive dialogue and reflects the drive towards more representative data practices influenced by societal movements. Ensuring that health care IT infrastructure meets needs for participation in a disease registry in underrepresented communities is critical to this approach. Systems (either funding or reporting) need to incorporate this into their design. No dataset will be without bias, but broad, regular engagement with the community a registry is intended to serve can help to mitigate it.[xlvi]

Enhancing research and data reporting in PD registries is pivotal for a comprehensive

understanding of the disease landscape. The key to this enhancement lies in developing inclusive data models that accurately capture social determinants of health and addressing historical inaccuracies and biases while remaining sensitive to historical disparities in treatment of PD.[xlvii] This approach involves redefining traditional data collection parameters to focus on a broader distribution of care, particularly for minority groups, thereby mitigating the trust deficit in data collection among these communities.[xlviii]The creation of new labels and models that accurately represent all demographics is crucial. By ensuring data equity and comparability, registries can better capture the nuances of PD, facilitating researchers, policymakers and stakeholders in making informed decisions.[xlix, l]

To this end, artificial intelligence (AI) can be employed for precise data analysis, aiding in identifying trends and discrepancies that are critical for evaluating the effectiveness of the registry. However, it is important to be cognizant of its potential pitfalls, including the ever-present risk of the data bias and the overestimation of its capabilities.[li] This approach underscores the notion that AI, while a powerful tool, must be used judiciously in PD registries. This is particularly true if AI is leveraged in attempts to improve data quality and decision-making processes, as historically, models may struggle to provide meaningful insight for underrepresented populations.

The following details essential metrics and KPIs for evaluating Parkinson's disease registries over their expected lifespan. These are intended to assess both registry functionality and strategic impact and should be continually evaluated for alignment with registry purpose and as registries reach each subsequent stage of maturity (basic, enhanced and aspirational). This is not an exhaustive list; an individual registry should align specific metric selection to registry purpose and should be reassessed regularly. While this list generally focuses on quantifiable measurements of registry performance, registries should also consider qualitative measures where appropriate. Registries should also consider whether there are any applicable local or national registry reporting frameworks that could inform specific metric selection, such as CDC's National Public Health Performance Standards.

Selecting metrics is important, but registries must also consider how to effectively convey the story told by the metrics to key stakeholders. For example, the South Carolina Alzheimer's registry provides fact sheets with statistics presented down to a county level, which is of considerable benefit to policymakers since they can see how their constituents are directly impacted. Easy-to-digest and short reports of registry activity and support are valuable tools to translate detailed internal registry health reports for a variety of audiences and build support for registry activities.

Use of Registries and Measuring Registry Performance

Data Quality & Integrity	Usage & Impact	Representation & Inclusivity	Operational Efficiency & Growth	Organizational Health
Data quality (completeness, timeliness, accuracy) Benchmark alignment	Usage (data requests) Purpose suitability (does it serve its intended use?)	Provider participation rates Source diversity (source type, location) Population representation (vs. collected demographics)	Reporting rates Solution uptime Growth of dataset (e.g., by participant or record count) Cost-effectiveness (e.g., return on investment)	Registry staff satisfaction

Functionality and Use

Your Registry

Strategic Impact

Implementation & Advancement	Diagnostic/ Therapeutic Improvements	Public Health & Epidemiology	Care Delivery & Accessibility	Research Enhancement
Meeting registry rollout milestones Policy impact tracking vs. disease reporting Use of data to support other public health initiatives Demographics of data users	Reduced time to diagnosis Increased frequency of diagnosis Measuring impact of interventions on outcomes Measuring impact of data on treatment development	Decreasing disease-associated complications Improving understanding of cost-of-care burden Lowering disability rates Resulting in public data analyses	Better allocation and availability of services Reduced time-to-access for care/specialists Care desert identification	Increasing amount of NIH funded research Additional publications on economic impact of disease Enhancing disease identification and provider engagement

Recommendations

Recommendations for Implementing Bodies

1. Develop guidance and requirements for integration of patient-generated health data (PGHD) into registries. Patient centricity is critical to building trust and enabling registries to mature and to meet an increasingly diverse and complex set of use cases. PGHD might include health history, treatment history, symptoms and lifestyle choices. This can also enable registries to achieve a more comprehensive overview of patient health.
2. Create guidelines defining "minimum necessary" data for public health purposes. Doing so enables data contributors to more easily and confidently engage with registries in a manner that is both HIPAA compliant and as minimally burdensome as possible.
3. Align on the appropriate KPIs and principles for measuring registry health across each stage of the maturity model. These KPIs should be reassessed on a regular basis, not only early in the design process but also as a registry prepares to move onto each subsequent step of the data maturity model. CDC's National Public Health Performance Standards or other state-mandated reporting requirements could support development of these KPIs.

Recommendations for Registry Operators

1. Establish and maintain advisory committees to engage with stakeholders and ensure integrations are sustainable over time. Committees should include a patient, a clinician, clinic employees interacting with EHR systems, members of public health organizations, registry operators, PD researchers and a representative from an advocacy organization. Set a regular cadence for them to meet, for solicitation of public comment, publicization of a roadmap and public celebration of wins to build trust.
2. Pursue a multi-source funding plan aimed at long-term sustainability. Funding may change or may not be guaranteed long-term, so it is critical to plan not only for registry rollout, but for creating a foundation that enables maturation moving forward. This includes targeting an array of funding sources, including but not limited to: public health or regulatory authorities (including at the state, regional and federal level), health care service providers, patient advocacy groups, clinician groups, academic institutions or consortia, professional societies and non-profits.
3. Provide easily understandable fact sheets and readouts for care providers and advocates. Providing simple, replicable, accessible and shareable resources enables you to advocate for and contextualize a registry's importance. It is also important to make these resources publicly available and publish updates regularly. These resources might include an overview of how data is collected, handled and used; the amount of data/number of registry participants; highlights such as the number of records, research progress or legislative updates; an overview of PD demographics in the state as collected by the registry or other program highlights.
4. Develop a communication plan enabling registries to be open with limitations of registry data. It is critical to provide guardrails against misuse or misinterpretation and empower stakeholders to engage with standard-setters and to push for the interests of the members of the PD community. While clear communication will not itself overcome missing or complete data resulting in misuse, it can help to draw awareness to potential pitfalls.

Recommendations for Stakeholders and Advocates

1. For MJFF (with assistance from standards-setters): Update model legislation to ensure that registries can receive automatically generated eICR pertaining to PD. This will require buy-in from the relevant public health authority but automatic receipt of eICR can help registries scale more quickly.
2. For CDC or CSTE: Serve as neutral convener for a national steering committee so that registry operators can collaborate to generate recommendations on technological standards for data collection, management, governance, transfer and systems integration. This includes enabling stakeholders to coalesce around standards discussed in this report (e.g., FHIR, USCDI, TEFCA).
3. For CDC or CSTE: Create a coalition of registries to amplify potential achievements and empower members to share best practices. This will also enable them to clarify the unique considerations and value of case reporting for chronic neurological conditions and potentially develop a shared phenotype across registries.
4. For all stakeholders: Create advocacy plans and shared resources, including guidance on funding, legislating and scaling. These plans should include strategies for securing funding, improving and leveraging model legislation and refining the maturity model as public health needs shift. Providing advocates with tools to communicate the challenges and value-add associated with registries will ensure that more stakeholders are working together effectively.
5. For all stakeholders: Create a "responsible PD registry framework" that covers issues of equity and privacy. Critical to this framework is to outline how to build mechanisms for soliciting and incorporating feedback from stakeholders on a recurring basis. Draw on preexisting models such as the NIH-wide strategic plan for diversity, equity, inclusion and accessibility or processes for establishing DEI committees to reduce planning burden.

Conclusion

As the number of states developing, deploying and improving their Parkinson's disease registries continues to increase, it is in our shared best interest to integrate the experience and expertise of those impacted by PD to continue to improve these efforts. By leveraging the full array of perspectives — from providers to patients and from researchers to regulators — in registry design and maturation, we can enable the improved provision of public health outcomes.

The ongoing success and utility of registries can be secured by pursuing design that emphasizes adaptability. Operators should start by determining desired outcomes and expecting them to change, rather than focusing on specific data elements or technologies, research outcomes or treatment options. By including a broad array of stakeholders throughout the design process, integrating feedback loops and effectively measuring registry performance in a manner attuned to community needs, we can build trust and provide value for those impacted by and interested in eradicating Parkinson's disease.

The persistent enthusiasm across both summits as well as in an increasing number of state legislatures around the country serves as a beacon for future collaboration. It promises that by working together, we can achieve far more than we can alone. In these interactions, the appetite for this work from policymakers, providers and people impacted by Parkinson's disease is apparent. There is every reason to believe that these efforts and the suite of resources that they have generated will provide stakeholders useful guidance and lead to not only the establishment, but the maintenance and growth of PD registries that serve the wider PD community.

Appendices

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