MS PATHS: Seeking to Enhance Multiple Sclerosis Care Through Emerging Technology, Clinical Innovation, and Continuous Learning
Commentary: Science Translational Medicine

CLINICAL RESEARCH

A Radical Proposal: Integrate Clinical Investigation into the U.S. Health Care System

Richard A. Rudick¹,²* and Delos M. Cosgrove³

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The health of the public depends on a healthy clinical research enterprise, and a healthy clinical research enterprise cannot develop if it is disconnected from the clinical care enterprise. The integration of a robust clinical research enterprise into the U.S. health care system is now, more than ever, a national priority, and a completely new approach is desperately needed.
MS PATHS: Demonstrating the Power of a Learning Health System

- Supported by Biogen, in collaboration with leading healthcare institutions
- Leverages technology and patient engagement to achieve standardized assessments to support clinical care and continuous learning

MS PATHS Shared Vision: By pooling data, this network of healthcare institutions will create a system of continuous learning—a way to learn from clinical practice and generate insights that can be used to inform decision making at the point of care.
MS PATHS Strategy and Objectives

- Ensure transparent governance by a multi stakeholder group
- Include all MS patients at participating healthcare institutions who choose to share de-identified data
- Collect standardized, quantitative data as part of patient visits
- Leverage technology and patient engagement to minimize provider burden
- Use separately consented within-network studies to leverage standard of care data
- Demonstrate value to patients, providers, payers, and other stakeholders
## MS PATHS Sites

<table>
<thead>
<tr>
<th>Institution</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleveland Clinic</td>
<td>Cleveland, Ohio</td>
</tr>
<tr>
<td>Johns Hopkins Medicine</td>
<td>Baltimore, MD</td>
</tr>
<tr>
<td>New York University</td>
<td>New York, NY</td>
</tr>
<tr>
<td>OhioHealth</td>
<td>Columbus, OH</td>
</tr>
<tr>
<td>University of Rochester</td>
<td>Rochester, NY</td>
</tr>
<tr>
<td>Washington University in St. Louis</td>
<td>St. Louis, MO</td>
</tr>
<tr>
<td>Cleveland Clinic Lou Ruvo Center for Brain Health</td>
<td>Las Vegas, NV</td>
</tr>
<tr>
<td>University Hospital of Giessen and Marburg</td>
<td>Marburg, Germany</td>
</tr>
<tr>
<td>University Hospital Carl Gustav Carus</td>
<td>Dresden, Germany</td>
</tr>
<tr>
<td>Vall d’Hebron University Hospital</td>
<td>Barcelona, Spain</td>
</tr>
</tbody>
</table>

US Sites: Contracted

EU Sites: Contracts in Process

As of 12/16
MS PATHS Components

1. Standardized data collection
   - Clinical data
   - MRI data
   - Biologic data

2. Data aggregation across healthcare institutions
   - Store, analyze, visualize data

3. Insights
   - Research
   - Point of care
Clinical Data: Multiple Sclerosis Performance Test

- iPad-based, commercial-ready Class I medical device
- Structured history based on NIH Common Data Elements for MS
- Neuro-QOL: Developed for MS by NIH as a sister project to PROMIS. Assesses 12 dimensions of health
- Four PerfO’s, measuring cognition, vision, manual dexterity, and walking (simulates Multiple Sclerosis Functional Composite)
2 minute movie goes here
MS PATHS Components

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2. Data aggregation across healthcare institutions
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3. Insights
   - Research
   - Point of care
### MRI

**Semi-Quantitative Assessment**
- New T2 lesion count (0, 1, 2, or ≥ 3)
- Gd-enhancing lesion count (0, 1, 2, or ≥ 3)

**Quantitative Assessment**
- New or enlarging T2 lesion count
- Brain volume & brain volume change

3D MPRAGE & 3D FLAIR images, 3T scanner

*To be developed.*

### Biobanking

- DNA sample
- RNA sample
- Serum sample
- EDTA whole blood sample
- Time of last meal
- Time of sample collection

### MyHealth

#### Demographics & Socioeconomics
- Gender
- Age
- Race and Ethnicity
- Education
- Handedness
- Employment Status
- Insurance
- Living Situation

### MS

- Age of MS SX onset
- Age MS DX
- MS Subtype
- Relapse(s) in past 12 months
- Last steroid use
- Current DMT and when started
- Previous DMT if applicable and when started
- Patient-Determined Disease Steps (PDDS)
- Mobility Aid

### Neurological Performance Data Elements

- Contrast Sensitivity Test
- Manual Dexterity Test
- Processing Speed Test
- Walking Speed Test

### Neuro-QoL

#### Mental
- Emotional Health (eg, anxiety, depression, stigma)
- Cognitive Health (eg, applied cognition - general concerns and executive function)

#### Physical
- Function/Health (eg, upper and lower extremity function)
- Symptoms (eg, fatigue and sleep disturbance)

#### Social
- Ability to Participate in Social Roles
- Satisfaction with Social Roles

### EMR Data Elements

- JCV antibody status
- Vitamin D levels
- Medication list
- Smoking status
- Time of last meal
- Time of sample collection

### Biobanking

- DNA sample
- RNA sample
- Serum sample
- EDTA whole blood sample
- Time of last meal
- Time of sample collection

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**CONFIDENTIAL**
Estimated MS PATHS Patient Number

Number of patients (000s)

- High enrollment
- Base enrollment
- Low enrollment
### Current Dashboard – Initial site

#### Weekly Opt-in

#### Study

<table>
<thead>
<tr>
<th>Study</th>
<th>Number</th>
<th>Unique Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>MSPT assessment</td>
<td>1580</td>
<td>1132</td>
</tr>
<tr>
<td>Imaging study</td>
<td>587</td>
<td>525</td>
</tr>
</tbody>
</table>

**358 patients with multiple MSPT assessments**

#### Amount of MRI Data

<table>
<thead>
<tr>
<th>Category</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Files</td>
<td>279,250</td>
</tr>
<tr>
<td>Data volume</td>
<td>39 Gb</td>
</tr>
</tbody>
</table>

Data current as of Dec 1, 2016
MS PATHS: Initial Lessons Learned

1. Conducting research as a part of patient care is a new concept to provider organizations and clinicians
2. Participants have been inspired by the vision (“this is the future of medicine”)
3. Achieving consensus among neurologists, radiologists, hospital IT specialists, and administration is challenging
4. Changing practice workflow and standardizing across practitioners and institutions requires significant commitment from institutions and clinicians
5. IT issues are daunting, and relate to institutional source systems, data security and privacy, integration with the MS PATHS infrastructure, and cost
6. Complete data collection is challenging in the clinical setting, because the objectives for clinical care and research are fundamentally different
7. No financing mechanism to scale this model
8. Much work to do, but early signs are positive
<table>
<thead>
<tr>
<th>LHS Value</th>
<th>Supports?</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person Focused</td>
<td>✔</td>
<td>All data elements considered important by patients and MS experts</td>
</tr>
<tr>
<td>Privacy</td>
<td>✔</td>
<td>Institutional privacy officers approved plans for privacy and security</td>
</tr>
<tr>
<td>Inclusiveness</td>
<td>✔</td>
<td>All patients invited to participate</td>
</tr>
<tr>
<td>Transparency</td>
<td>✔</td>
<td>Academic partners developed governance and transparency policies</td>
</tr>
<tr>
<td>Accessibility</td>
<td>?</td>
<td>Data accessible to participating healthcare institutions and Biogen</td>
</tr>
<tr>
<td>Adaptability</td>
<td>?</td>
<td>Too early to tell</td>
</tr>
<tr>
<td>Governance</td>
<td>✔</td>
<td>Academic partners developed governance and transparency policies</td>
</tr>
<tr>
<td>Participatory</td>
<td>✔</td>
<td>Steering committee includes academic partners, patient advocate</td>
</tr>
<tr>
<td>Leadership</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scientific Integrity</td>
<td>✔</td>
<td>All participants agree that scientific integrity is fundamental to the project</td>
</tr>
<tr>
<td>Value</td>
<td>?</td>
<td>MS PATHS will determine value per RTI evaluation plan</td>
</tr>
<tr>
<td>Data Standards</td>
<td>✔</td>
<td>Foundational for systematic learning. Should be a core value for LHS</td>
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</tbody>
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