

Improving Quality and Value of Multiple Sclerosis Care at the Microsystem Level:
The Multiple Sclerosis Continuous Quality Improvement (MSCQI) Research Collaborative

Objective: To establish the first systems level continuous quality improvement (QI) collaborative for multiple sclerosis (MS) in the United States, to conduct benchmarking analyses of geographic variation in MS care quality and value, and study the effect of QI interventions on improvement of selected performance indicators.

Specific Aims:

1. To establish system-level performance indicators by obtaining quarterly performance measures aggregated by MS center/clinic (microsystem) and the entire collaborative.
2. To conduct studies of variation in performance across microsystems and to utilize benchmarking analyses to identify top performers.
3. To study the comparative improvement of primary endpoints over a 3 year period in microsystems receiving QI versus those not receiving QI intervention, and between two different QI interventions (IHI Breakthrough Series vs. Patient Centered Specialty Medical Home).

Design: This is a three year prospective study which will employ a step-wedge randomized design. We will expose three of four participating MS centers to one of two healthcare QI interventions during the 3 year period: (1) IHI Breakthrough Series with Improvement Coaching; and (2) Patient Centered Specialty Medical Home. Each of the MS centers exposed to an intervention will serve as its own control during a baseline pre-intervention period during the first year of the study prior to exposure to the interventions in Years 2-3. The fourth site will serve as a longitudinal control for comparison to the other three centers exposed to a QI intervention. Data from participating centers will be de-identified and aggregated to the center level and collected quarterly throughout the study period.

Endpoints: The primary endpoint for this study is the percentage of eligible MS patients on any type of MS disease modifying therapy (DMT), which is operationally defined as the total number of eligible patients on a DMT divided by the total number of patients seen per quarter at a participating center for whom DMT is an indicated treatment option. Secondary endpoints include: (1) clinical process and outcome measures; (2) functional health measures; (3) patient experience measures; and (4) cost and utilization measures.

Current MSCQI Collaborative Entities: Four multiple sclerosis centers are participating in the study: 1) the MGH Multiple Sclerosis Clinic (Boston, MA); (2) the University of Vermont Multiple Sclerosis Center (Burlington, VT); (3) Concord Hospital MS Specialty Care Program (Concord, NH); and (4) the Multiple Sclerosis Center of Greater Orlando (Orlando, FL). Participating MS Centers in the MSCQI Collaborative follow approximately 6,000 adults with multiple sclerosis. This number will increase as the collaborative now has funding support to add four additional sites to increase the Collaborative to a total of eight (8) centers nationally. This study aims to recruit approximately one-quarter to one-third of the population followed by each participating center. Study sites will be coordinated and overseen by a core research team at the Dartmouth Research Collaboratory for Improvement, Implementation and Innovation Science (Dartmouth College, Hanover, NH) and supervised by the principal investigator. Data management and analytics will be conducted by DeltaQuest, LLC (Concord, MA).

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Participation: There are two levels of participation in this study: (1) system level administrative; and (2) individual level clinical.

1) System Level and Administrative: The first level of participation is at the system level. It requires quarterly reporting of de-identified administrative data aggregated to the system level. This data includes covariates such as payer mix and other relevant variables which will be used to adjust between centers. It will also include de-identified data regarding the proportion of patients seen each quarter who are on any DMT, and MRI utilization. This level of participation does not include the collection or use of protected health information (PHI) and will not require informed consent.

2) Individual Level Clinical: This level of participation requires individual patients to complete self-report questionnaires administered via a secure online patient reported outcomes (PRO) portal. Data collection at this level will via an online platform accessible by smartphone or internet staggered at monthly to quarterly intervals. This will include the collection of PHI and will require an informed consent process.

Inclusion and Exclusion Criteria for Individual Level Participation: Adults aged 18 years or older with documented clinically confirmed multiple sclerosis (MS) who are followed by one of the participating MS centers are eligible for study participation.

1) Inclusion Criteria:

- documented diagnosis of multiple sclerosis (MS);
- age 18 years or older; and
- ability to read and understand the Informed Consent Form which describes the purpose and potential risks of study participation.

2) Exclusion Criteria: Candidates will be excluded if they decline to provide informed consent or opt out of study participation.

Data Analytic Plan:

1) Specific Aim 1: To establish systems-level quality and value indicators we will obtain quarterly performance measures, aggregated by MS clinic (system) and the MSCQI Collaborative as a whole. Descriptive statistics will be conducted to describe basic system-level variation in primary endpoint measures (DMT and MRI) and selected secondary endpoint measures from each of the major balanced measurement domains (clinical, functional health, patient experience, and utilization). Measures will be adjusted based on appropriate system level structural and individual level demographic characteristics which demonstrate statistically significant relationships with the dependent variable in univariate analyses.

2) Specific Aim 2: To conduct studies of geographic variation in performance across MS clinics (microsystems) and utilize benchmarking analyses to identify top performers, we will use hierarchical linear modeling (HLM) to assess comparative performance and the effects of geographic location. To assess the importance of geographic variables, three types of models will be compared: (1) a model with individual level variables only; (2) a model with system level

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geographic effects that do not interact with person attributes; and (3) a full model, allowing for geographic level random effects that differ by site. The Available Benchmarks of Care (ABC) method can be utilized to benchmark variables that demonstrate substantive variation in key process or outcomes performance and to identify top performing sites by performance category.

3) Specific Aim 3: To test the effect of QI interventions, we will use longitudinal time series regression analyses. DMT access will be treated as the DV and compared between baseline and quarterly intervention time periods during Years 2-3 overall and stratified by intervention. For univariate comparisons, we will use Chi-Square tests for categorical data and Student t-tests for continuous data. For multivariate analyses, we will conduct multilevel XTME Poisson regression clustering to the center level to calculate adjusted risk ratios (RR) with 95% confidence intervals of the dependent variable measure between the intervention and baseline periods, adjusting for important system level structural and individual level demographic characteristics. To demonstrate temporal trends in performance, we will use interrupted time series analyses of quarterly performance rates adjusting for covariates in the Poisson model.

Human Subjects: This study will not directly apply any experimental exposure to participants, alter the sanctity or autonomy of the patient-provider relationship, or dictate the frequency or patterns of care for people participating in MS care at participating MS centers. For this reason, this study is estimated to incur minimal risk and no greater risk than that incurred when engaging in standard health care for multiple sclerosis. This study has been approved as an expedited review minimal risk research study by the Dartmouth CPHS Institutional Review Board. Participating sites may defer IRB review to Dartmouth CPHS or opt for independent IRB review based on local IRB preference.

Implications: MS currently has no cure, is among the most common neurological disorders in the United States, is extremely costly to individuals and healthcare systems, lacks optimally effective treatments and substantially impacts disability. Optimizing the quality and value of system-level healthcare delivery in MS is essential to maximize outcomes for people with MS and to demonstrate the value of MS care. Additionally, the investigation of the comparative effectiveness of system-level QI interventions and the effects of QI intervention on patient experience and functional health represents an entirely new area of investigation in MS that is complimentary to other established methodologies (i.e. clinical trials and population studies focused on clinical outcomes). Finally, this improvement research collaborative, which is the first of its kind in the United States, will create a new learning community which can drive the future expansion, replication, and longitudinal study of QI in MS care and contribute to discourse and advocacy efforts related to health policy issues affecting MS care.