A. Title Page

Title of Project: Quality Improvement and Practice-Based Research in Neurology Using the EMR

Principal Investigator and Team Members:

University of Florida:
Demetrius M. Maraganore, MD (principal investigator)
Amber Miller, MPH (study coordinator)

NorthShore University HealthSystem:
Steven L. Meyers, MD (subcontract PI)
Richard Chesis (senior applications analyst)
Alexander Ephsteyn (senior programmer analyst)
Anna Pham (study coordinator)
Naitik Shah (senior application analyst-specialist)
Samuel Tideman (data scientist)
Gary Wilk (data scientist)

Organization: University of Florida (primary), NorthShore University HealthSystem (subcontract)
Inclusive Dates of Project: 07/01/2015 – 04/30/2020
Federal Project Officer: Noel Eldridge
Acknowledgment of Agency Support: R01HS024057

B. Structured Abstract

Purpose: The Department of Neurology at NorthShore University HealthSystem (NorthShore) built into its commercial EMR structured clinical documentation support (SCDS) and clinical decision support (CDS) tools that standardize care, write progress notes, and capture up to 1,000 discrete and cascading fields of data per office visit. However, the EMR tools had not been disseminated for use by other Neurology practices or for data sharing and did not support clinical trials. Pragmatic trials using EMRs would enable comparisons of treatments at the point of care.

Scope: We created a national network for quality improvement and practice-based research in Neurology by sharing EMR tools and creating a data registry. We demonstrated the feasibility of subgroup based adaptive assignment of treatments, electronic consenting, and outcomes data capture at the point of care using the EMR.

Methods: To address gaps in quality improvement and practice-based research in Neurology, we had two aims: 1) We aimed to create a Neurology Practice-Based Research Network. The NorthShore site shared SCDS and CDS tools for 10 common neurological disorders with other Neurology Departments that also use the Epic EMR platform. 2) We also aimed to conduct at NorthShore pragmatic trials using the EMR for common neurological disorders.

Results: The EMR was employed effectively to improve healthcare quality by accelerating implementation of patient-centered outcomes research in Neurology, making healthcare safer and of higher quality and efficiency (consistent with AHRQ's mission and priority areas of focus).

Key Words: Electronic Medical Record, Practice Based Research, Pragmatic Trials

C. Purpose

Objectives of Study: The **goals** of the proposed research were to advance quality improvement and practice-based research in Neurology using the EMR.

To address gaps in quality improvement and practice-based research in Neurology, we submitted to the Agency for Healthcare Research and Quality (AHRQ) a grant application with the **Specific Aims (objectives)**:

1) *To create a Neurology Practice-Based Research Network (NPBRN).* The NorthShore site shared SCDS and CDS tools for 11 neurological indications (brain health, brain tumors, concussion, headache, epilepsy,

memory disorders, multiple sclerosis, neuropathy, Parkinson's disease, sleep disorders, and stroke) with 12 other Neurology department sites that also use the Epic EMR platform. The NPBRN shared de-identified data for quality improvement and comparative effectiveness research. Table 1A in the original grant application (see Research Strategy/Project Narrative) provided examples of quality improvement projects that the sites might perform. Quality improvement was an **expected outcome** of this goal.

2) *To conduct at NorthShore pragmatic trials using the EMR for three common neurological disorders.* Table 2 in the original grant application (see Research Strategy/Project Narrative) listed the disorders, treatments, and patient-centered outcomes that we might study. We aimed to demonstrate the feasibility of subgroup-based adaptive assignment of treatments, electronic consenting, and outcomes data capture at the point of care using the EMR. We aimed to identify the most effective treatments for common neurological disorders and define "Next Practices" to build into the SCDS and CDS tools for replication and dissemination by the NPBRN. Practice-based research was an **expected outcome** of this goal.

Impact: Our aims were **innovative** because we used the EMR to hardwire quality and outcomes research in Neurology. We individualized medicine at the point of care by conducting pragmatic trials, using a subgroup-based adaptive design, comparing the effectiveness of treatments for common neurological disorders. Our aims were **significant** because we studied several neurological disorders, recognized as a leading cause of healthcare burden worldwide {http://www.who.int/mental_health/neurology/neurodiso/en/}. We created a national network for quality improvement and practice-based **patient-centered outcomes research** in Neurology using EMR tools to create a data registry and using evidence to **make healthcare safer** and to **improve healthcare efficiency**, in keeping with the mission and priority areas of AHRQ.

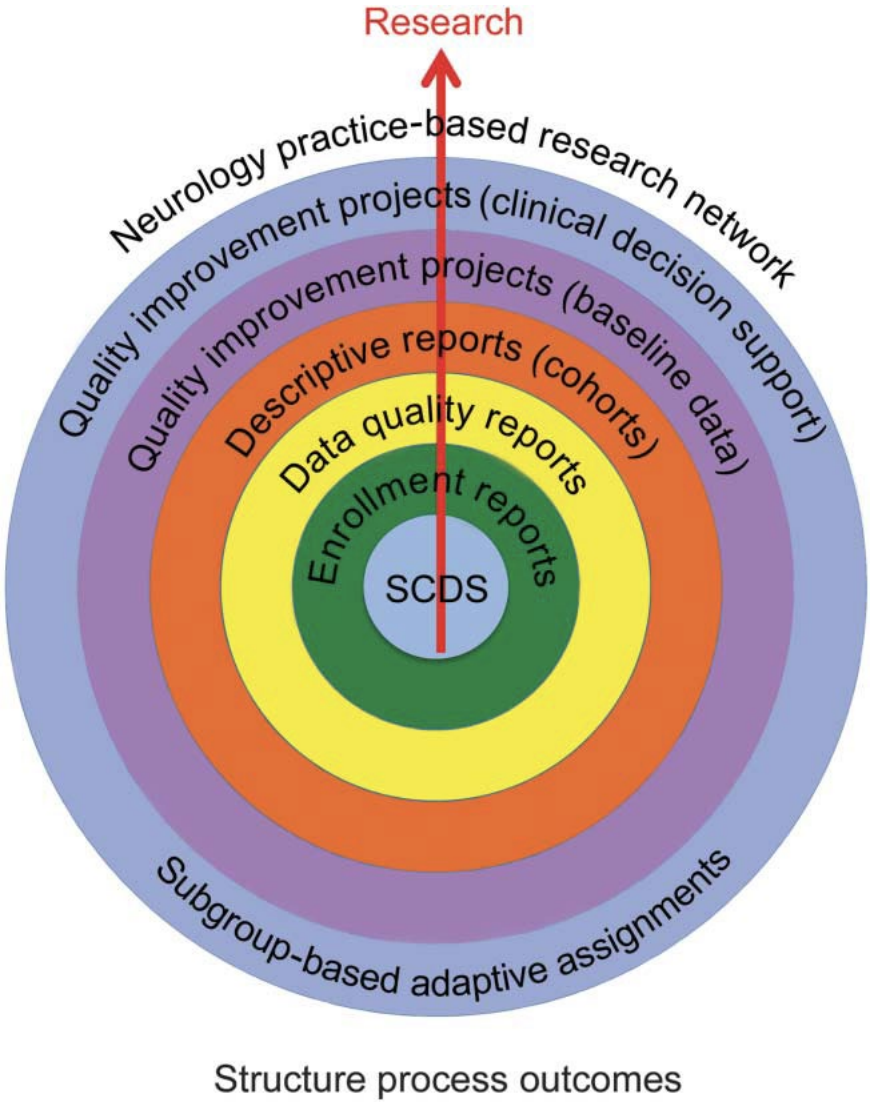
D. Scope

Background: The goals of the proposed research were to advance quality improvement and practice-based research in Neurology using the EMR.

Context: The American Academy of Neurology (AAN) has published evidence-based guidelines for several neurological disorders and similarly published quality improvement measures and resources. However, the AAN guidelines and measures have not been implemented routinely, and benchmark data are lacking. There are few EMR tools available to standardize neurology office visits according to Best Practices, to provide alerts when neurological care is deviating from AAN guidelines, to capture data regarding adherence to AAN or other quality parameters, to measure the effects of compliance with guidelines on outcomes, or to share longitudinal data and to compare effectiveness of care across neurological practices. Furthermore, commercial EMRs provide limited support for pragmatic clinical trials comparing the effectiveness of treatments at the point of care.

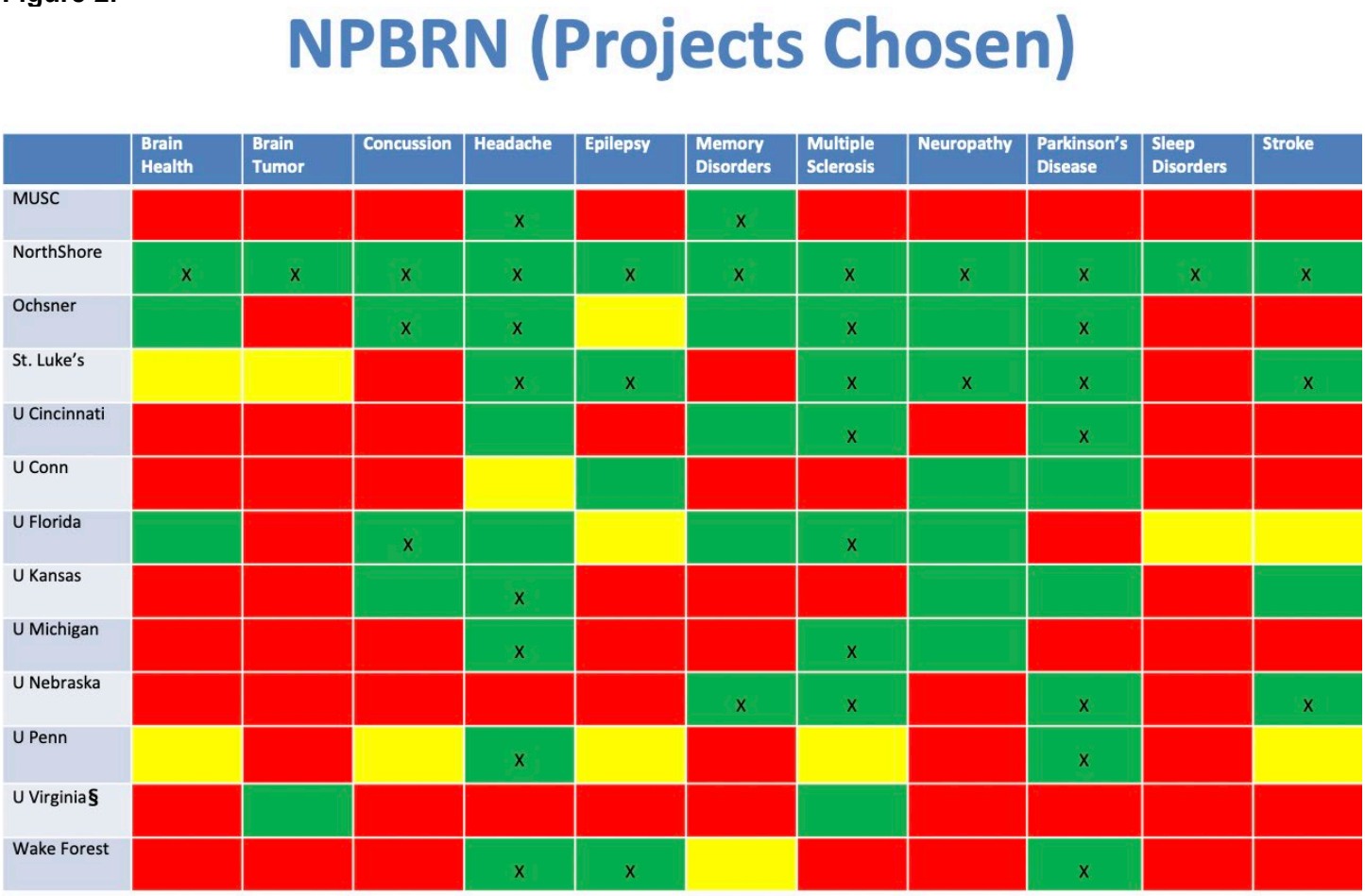
Settings: The Department of Neurology at NorthShore University HealthSystem (NorthShore) built into its commercial EMR "Epic" 11 SCDS and CDS toolkits (one for each of 11 neurological indications) that standardize care, write progress notes, and capture up to 1,000 discrete and cascading fields of neurological data per office visit. The NorthShore site also built EMR tools that randomly and adaptively assign patients to compared treatments, document informed consent, and capture outcomes at the point of care. The EMR-based approach to improve quality in neurology clinical practice is illustrated by **Figure 1** below.

Figure 1.



Participants: Aim 1: **Figure 2** below indicates alphabetically the 13 participating sites (rows), and the 11 shared toolkits (columns). Green cells indicate toolkits selected by the site for implementation, yellow cells indicate toolkits that were being considered, and red cells indicate toolkits not selected. Within the cells, the symbol “X” indicates that the toolkit was actually implemented. Apart from one site (the University of Virginia), all sites executed license agreements, data use agreements, and IRB approvals.

Figure 2.



With respect to Aim 2, the NorthShore site conducted pragmatic clinical trials using the EMR and subgroup-based adaptive designs comparing treatments for three disorders: migraine, mild cognitive impairment, and epilepsy. The second aim by design was unique to NorthShore.

E. Methods

Study Design:

Neurology Practice-Based Research Network (Aim 1): The NorthShore site shared SCDS and CDS toolkits for 11 common neurological indications (see Table above) with 12 other NPBRN sites that also use the Epic EMR platform (http://www.epic.com) under a free license. Sharing of EMR tools was with Epic's approval. The installation of EMR toolkits and implementation of clinical workflows was done by each site at their own effort.

The NPBRN sites shared the de-identified data captured by the EMR toolkits into a registry maintained by NorthShore. This included data from initial, interval, and annual follow-up visits. The smart data elements (structured fields and variables) built into the shared EMR tools (documentation flowsheets, smart forms) captured discrete data into Clarity (Epic's relational database), and the data were then extracted, transformed, and loaded (up to 1,000 fields per office visit) using a common data format in a central data repository. Data was submitted weekly to the registry by the NPBRN sites and was the object of constant monitoring.

For each EMR toolkit that was in use by two or more NPBRN sites, the NorthShore team created a quality improvement dashboard of graphs and monthly quality improvement reports so as to track the use of the toolkits at each site and overall and for the required measures to address missing values, inconsistencies, errors and other issues to be corrected by the participating NPBRN sites. Each participating site was granted login access to the de-identified quality improvement reports that were updated monthly. User groups for each toolkit met every other month to request revisions to the toolkits or data registry and to envision specific quality improvement projects. A statistician was assigned to perform descriptive analyses (e.g., analyses of variance, linear regression, chi-square tests) and longitudinal analyses (e.g., linear mixed models, generalized linear

mixed effects models, Kaplan-Meier plots, Cox proportional hazard models) as requested. The NPBRN Council, consisting of two lead physicians from each site, met every other monthly to monitor the activities of user groups and sites. The data hub architecture for the NPBRN registry is illustrated by **Figure 3** below.

Figure 3.

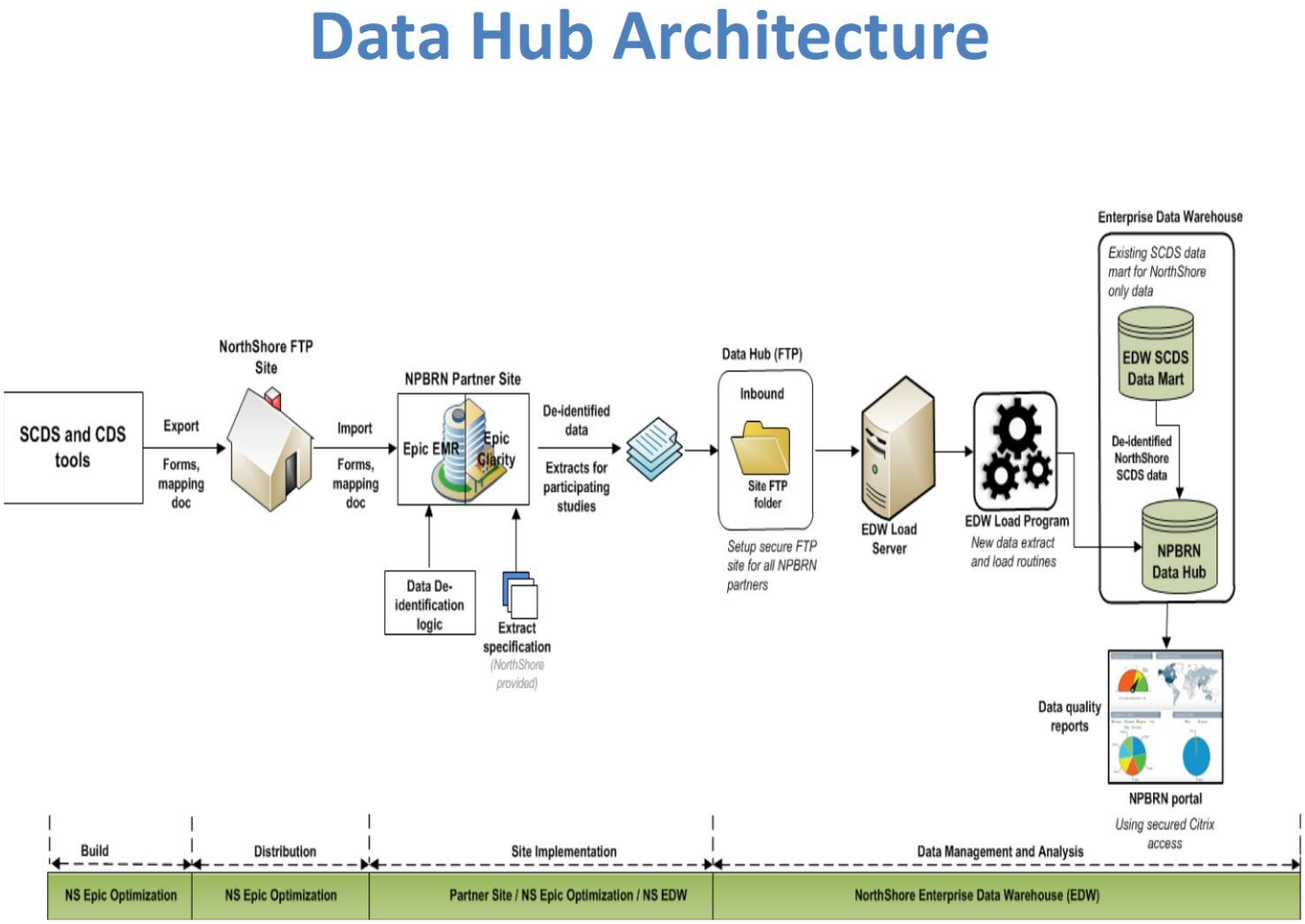
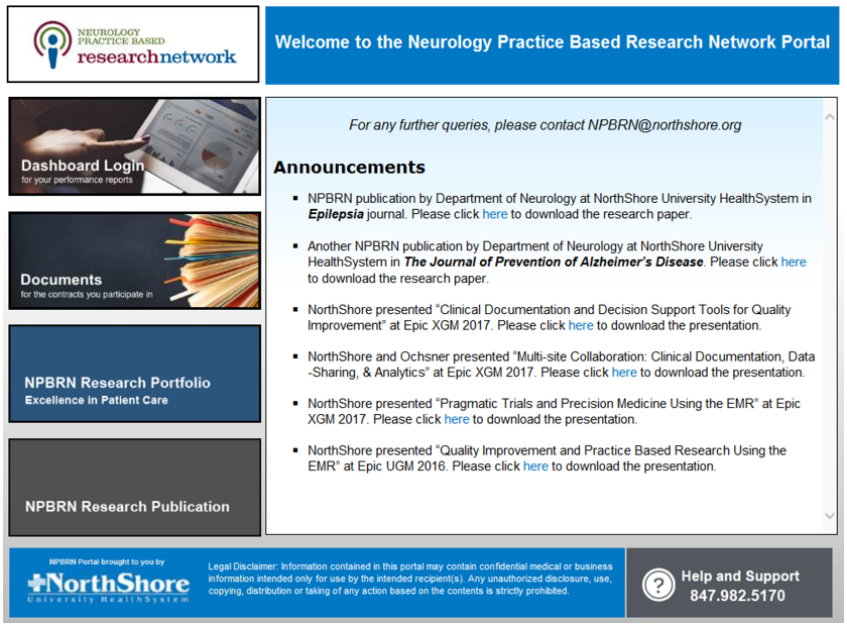


Figure 4.

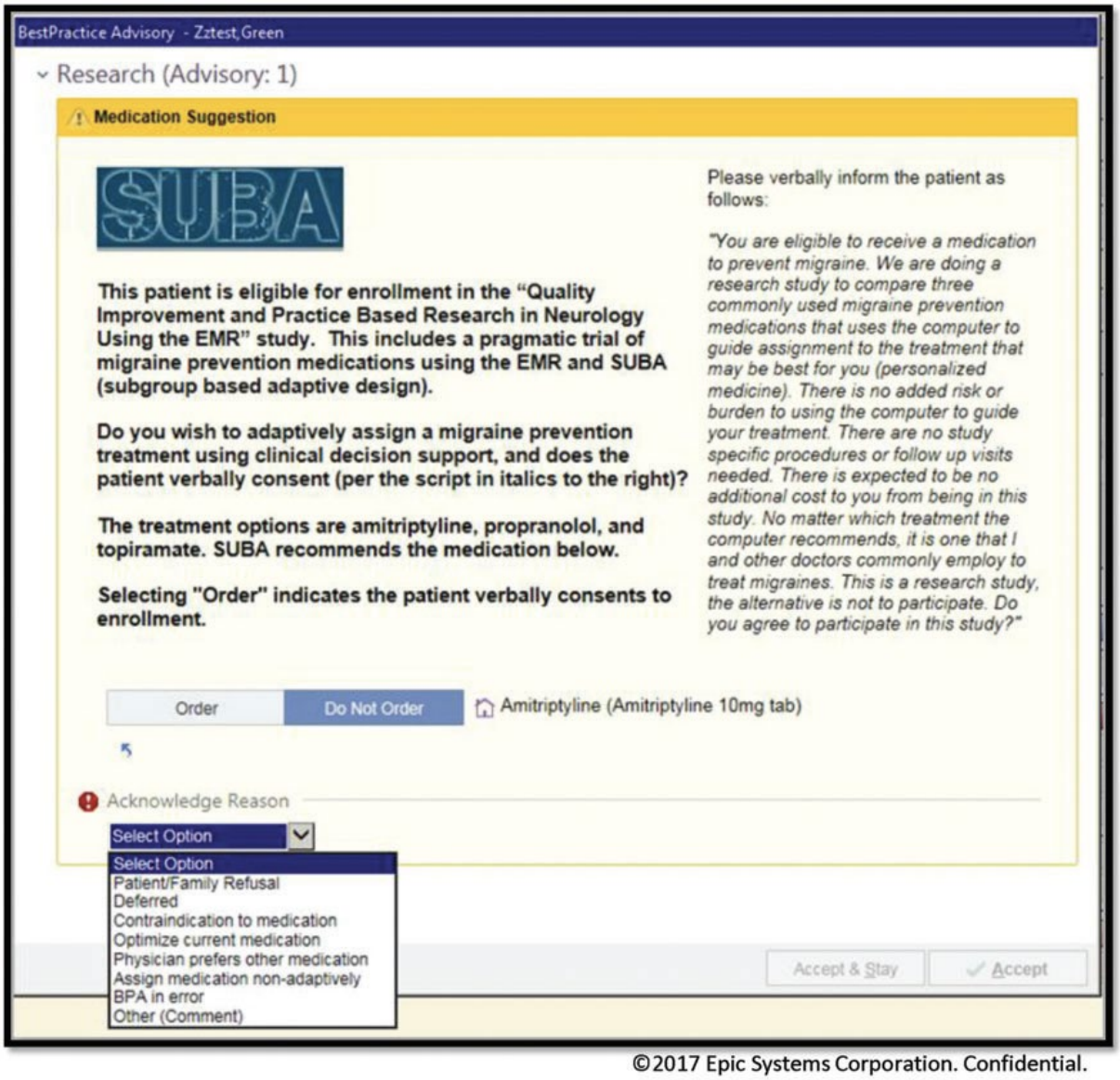


The adjacent **Figure 4** below illustrates the home page for the NPBRN registry, including announcements, dashboard login, an archive of documents (license agreements, data use agreements, IRB approvals), a portfolio of news releases and presentations, and all peer-reviewed publications.

Subgroup-Based Adaptive Design and Analysis of the Data (Pragmatic Trials, Aim 2): Our SCDS and CDS tools used discrete data to trigger alerts that prompted assignment to compared treatments at the point of care for three neurological indications: migraine prevention, dementia prevention in patients with mild cognitive impairment, and seizures prevention in patients with partial epilepsy. We employed a subgroup-based adaptive design (SUBA) that uses data captured from the previously enrolled patients to identify subgroup effects and to assign newly enrolled patients to treatments that are expected to be more effective for them (providing individualized medicine at the point of care). The main statistical features of SUBA include the continuous learning of patient subgroups based on a random partition model and the adaptive allocation of patients to the best treatment arm based on posterior predictive probabilities. We randomized 100 patients and then adaptively assigned at least 200 additional patients into each of the three comparative effectiveness trials. We captured outcomes data at initial, interval, and annual visits over 5 years. SUBA has shown desirable performance in computer-simulated trials with a sample size of 300.

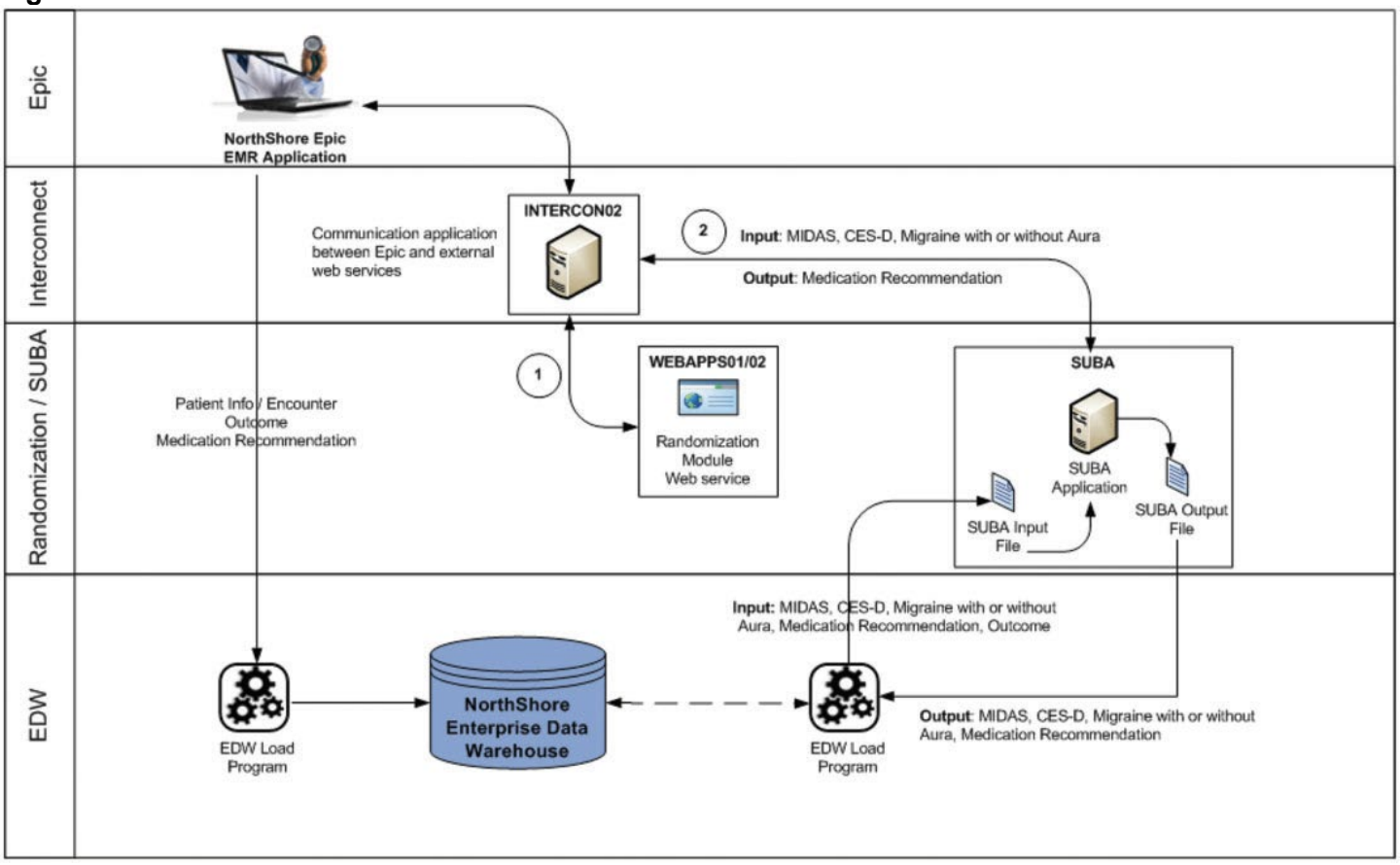
Figure 5 below illustrates the Best Practice Advisory (BPA) that alerted the physicians that a given patient was eligible for enrollment in a comparative effectiveness pragmatic trial that assigned a treatment (either randomly or adaptively) and scripted and documented informed consent.

Figure 5.



The additional **Figure 6** below illustrates the data workflow implemented in the SUBA trial for migraine. Additional information regarding the other two pragmatic trials (mild cognitive impairment, epilepsy) have been published (see references below).

Figure 6.



Measures:

Neurology Practice-Based Research Network (Aim 1): Each of the 11 EMR toolkits (SCDS and CDS tools for the evaluation and management of 11 neurological indications) captured several hundred discrete data elements per office visit. To prioritize quality improvement and practice-based research in Neurology, we convened, for each toolkit that was implemented by two or more sites, bimonthly user group meetings. The user groups selected for a given toolkit the required data elements for each initial office visit and for annual follow-up visits. Generally, this required documentation of the visit type (initial, interval, annual), the final diagnosis, and any standardized score test measures (including patient entered questionnaires and clinician assessments). We published several papers describing our 11 toolkits (see references). As an example, for the evaluation and management of headaches, the EMR toolkit included patient-entered questionnaires to evaluate migraine severity (MIDAS) and migraine-specific quality of life (MSQ) as well as to screen for anxiety (GAD-7), depression (CED-D), and insomnia (ISI). As another example, for the evaluation and management of memory disorders, the EMR toolkit included patient entered questionnaires to evaluated basic and instrumental activities of daily living (Barthel Index, Functional Activities Questionnaire) and a screening test for mood disorder (Geriatric Depression Scale). The toolkit also included standardized clinical assessments, such as mental status evaluations for cognitive impairment (Short Test of Mental Status, Montreal Cognitive Assessment) and a motor scale for parkinsonism (Unified Parkinson Disease Rating Scale). **Figure 7 (A-G)** below illustrates all of the quality measures that were required, for all sites combined, and the completion rates per measure.

Figure 7A. Epilepsy

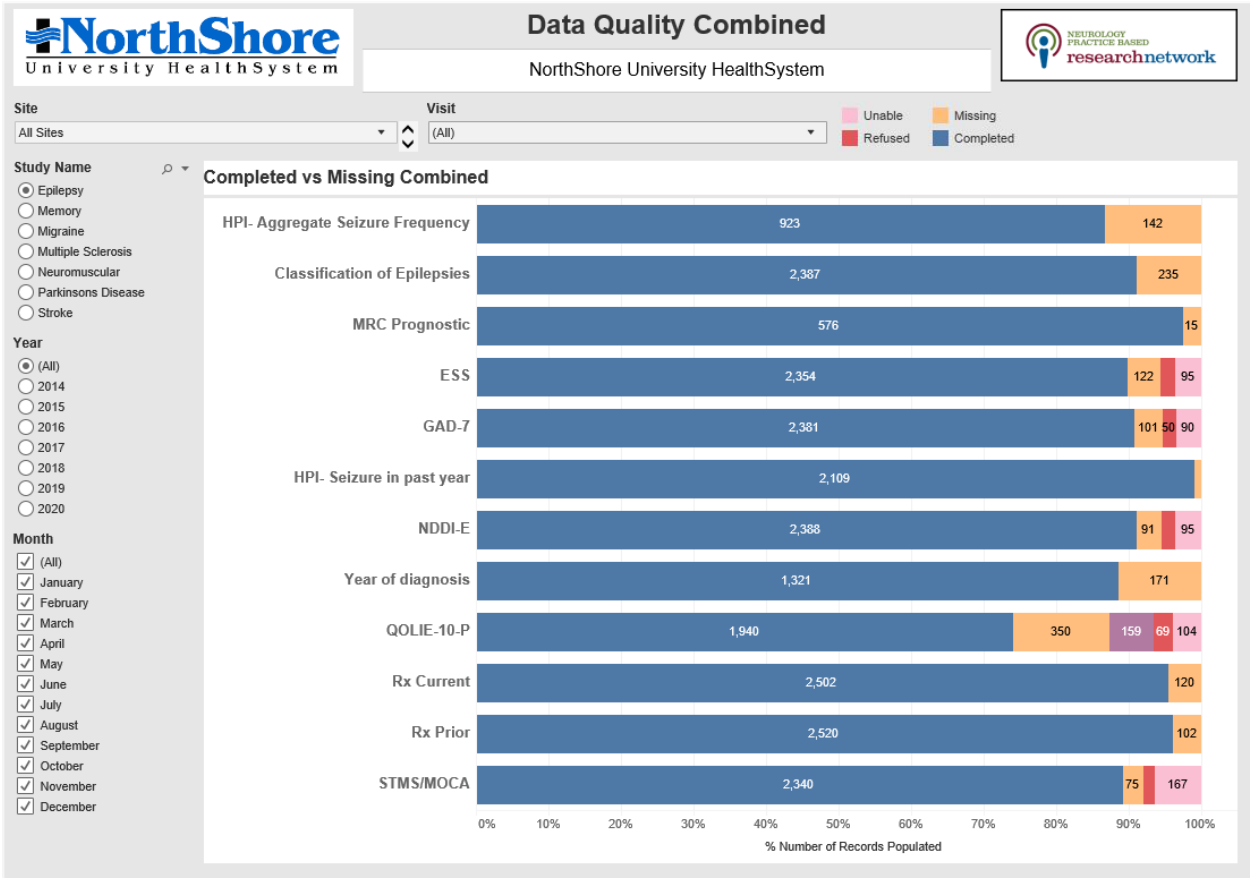


Figure 7B. Memory

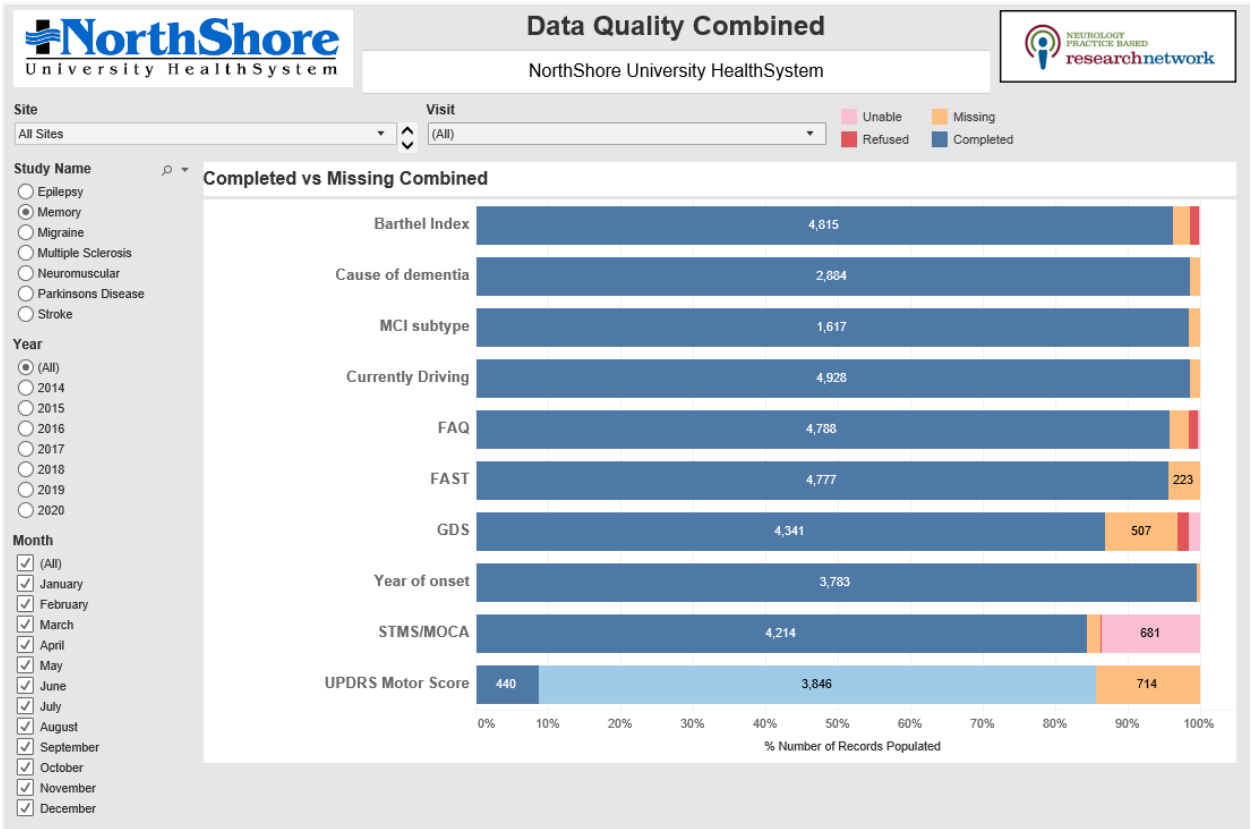
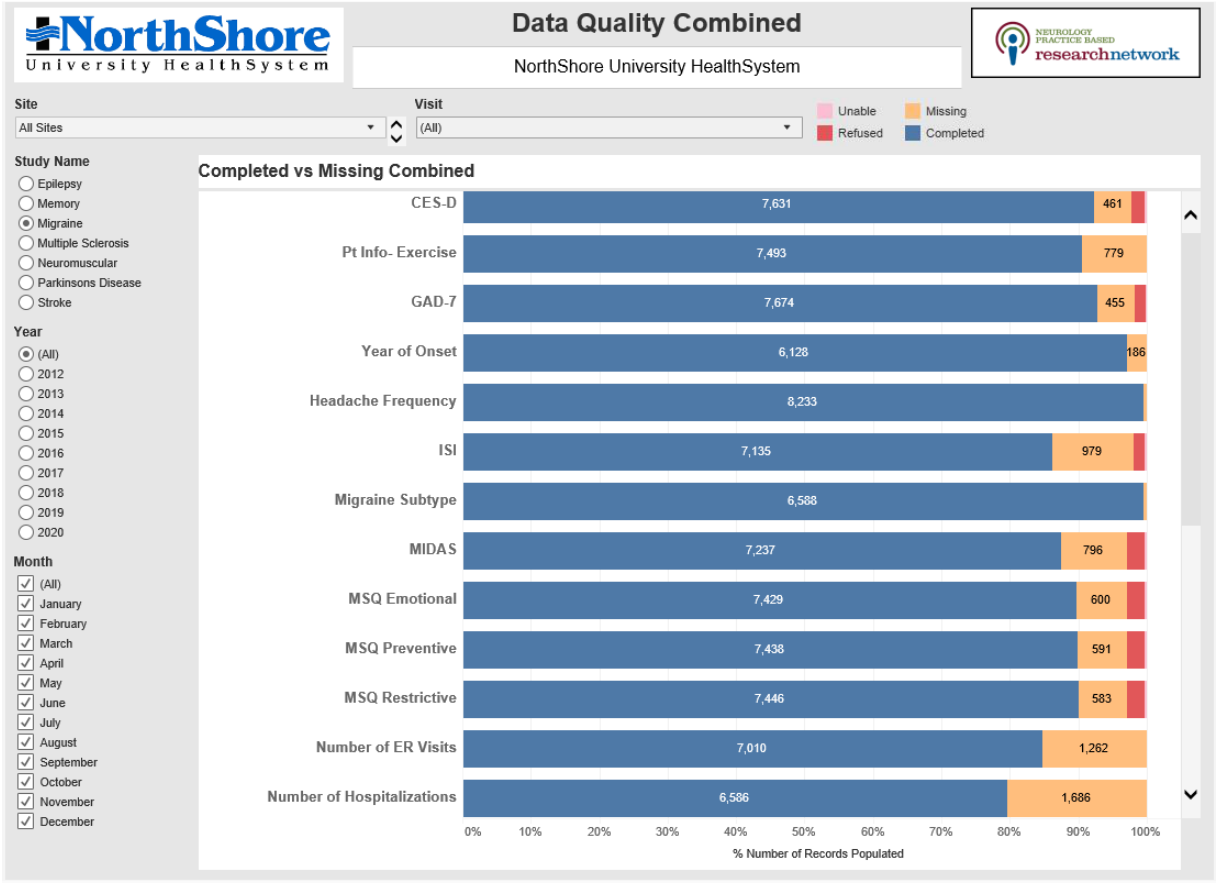


Figure 7C. Migraine



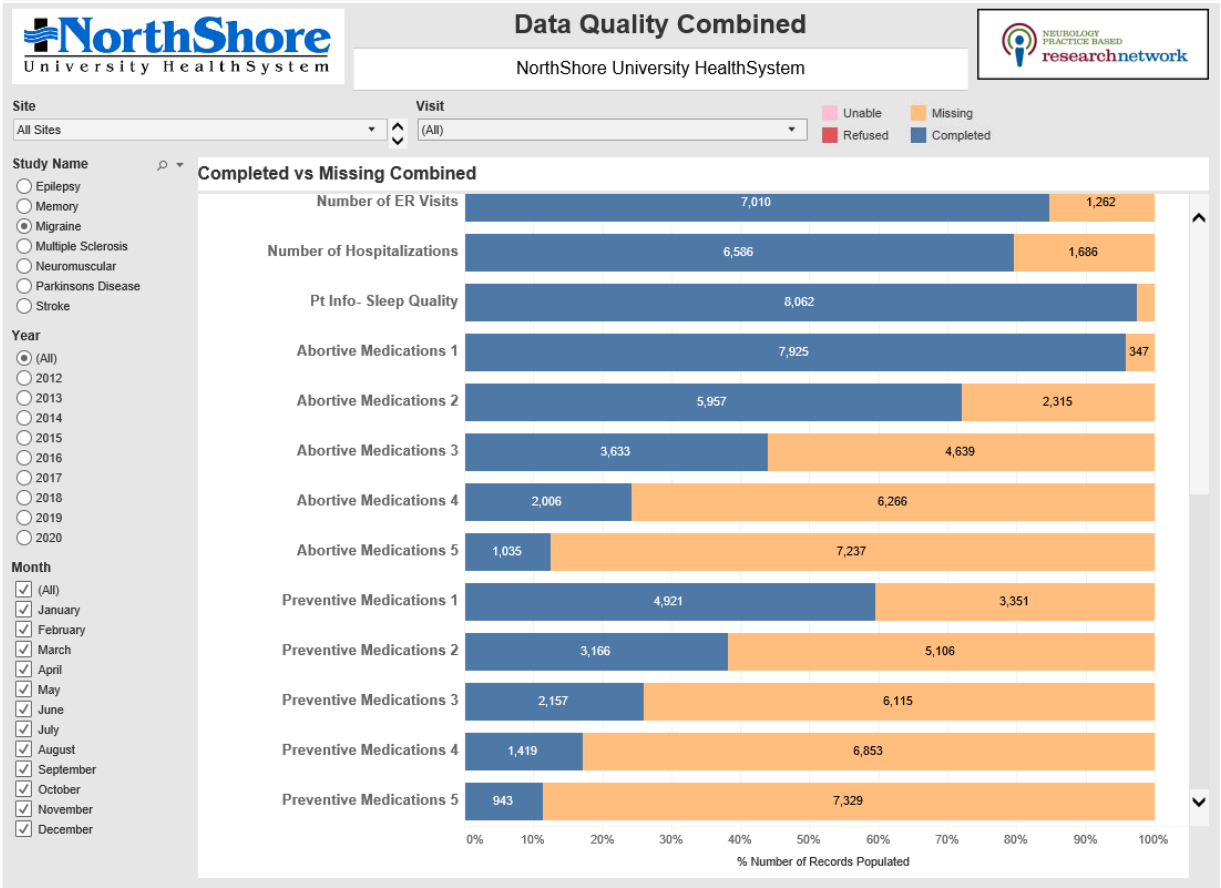


Figure 7D. Multiple Sclerosis

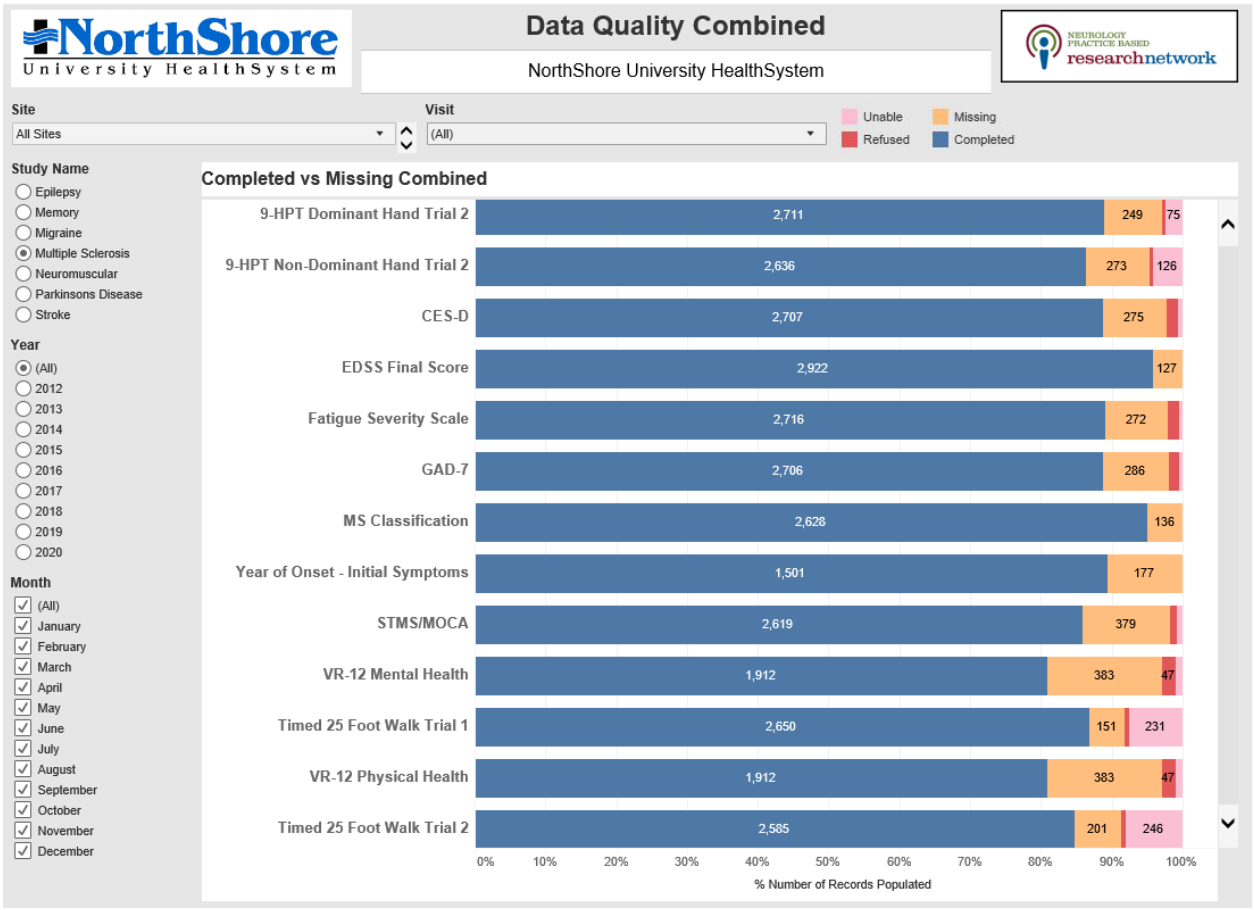
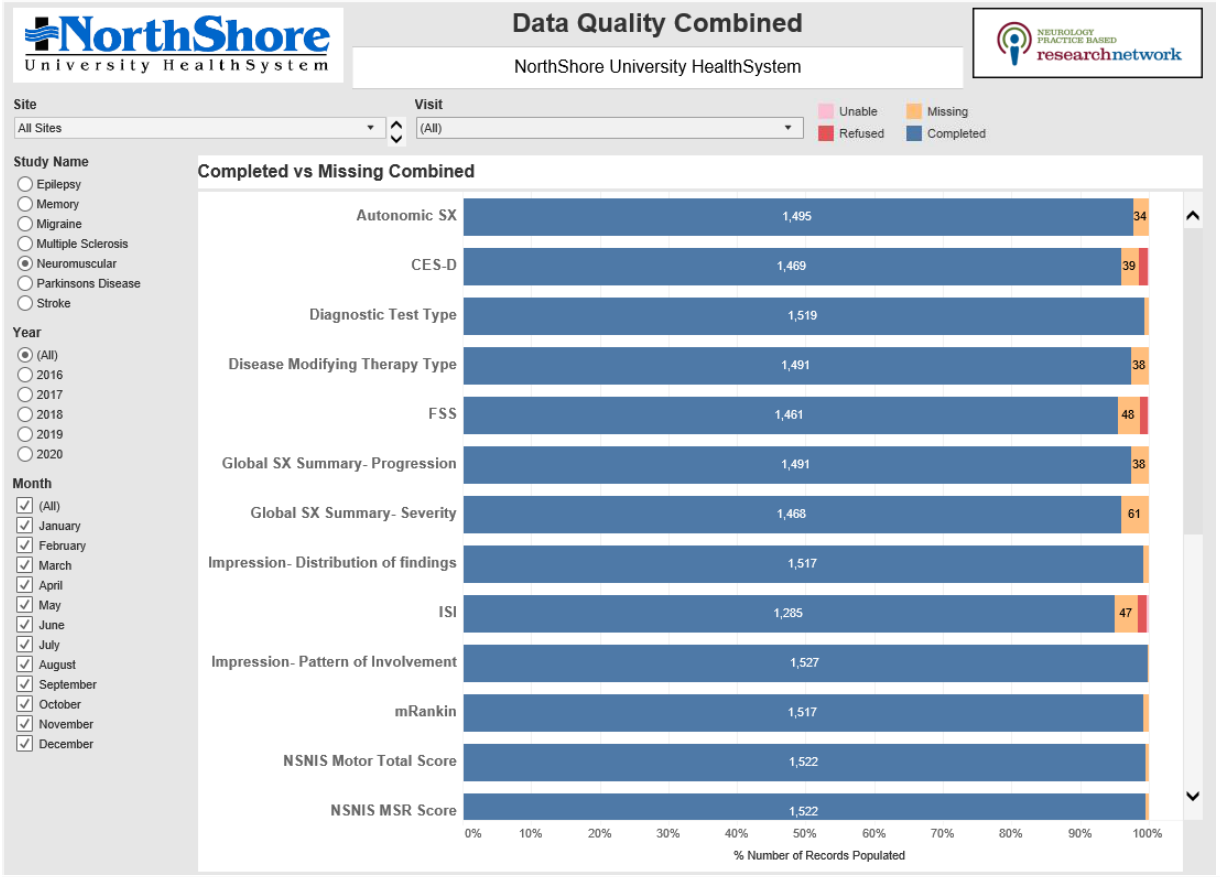


Figure 7E. Neuromuscular



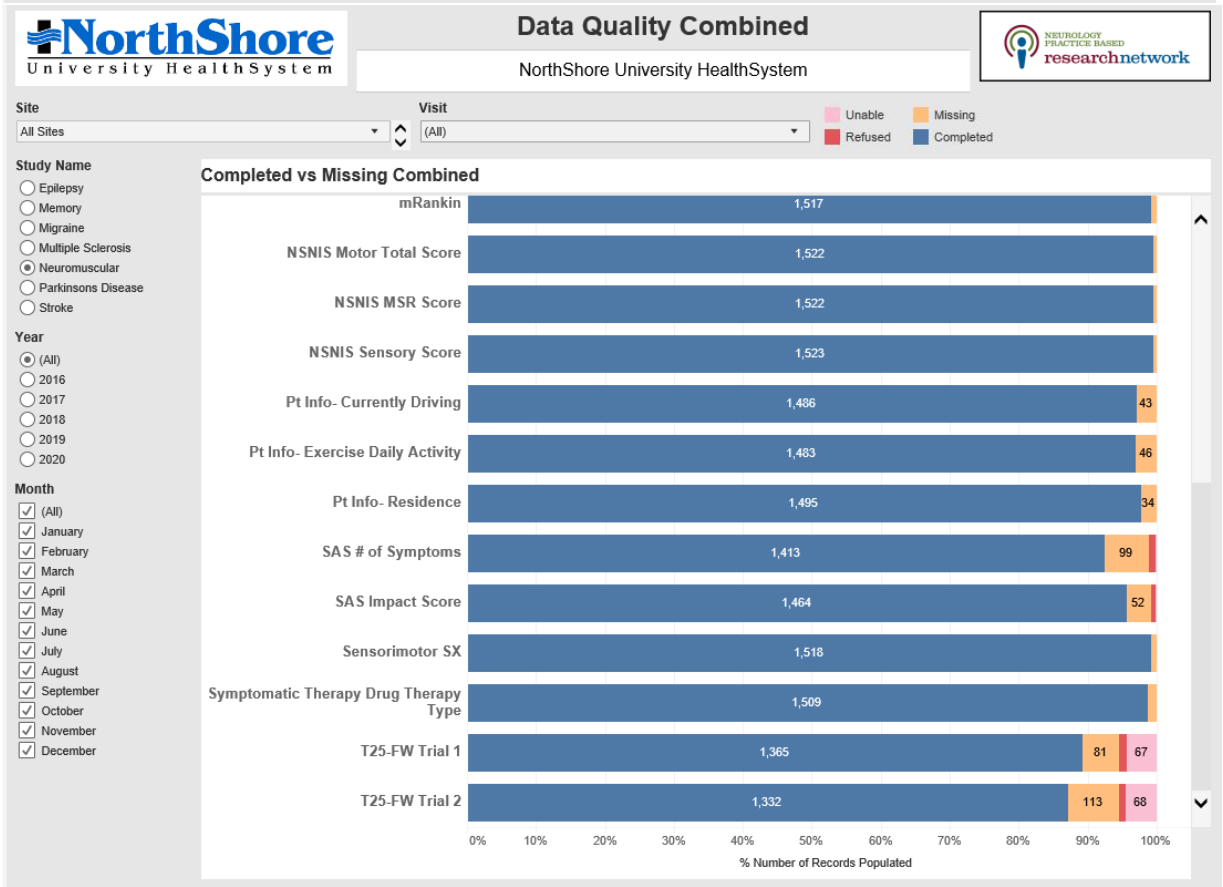
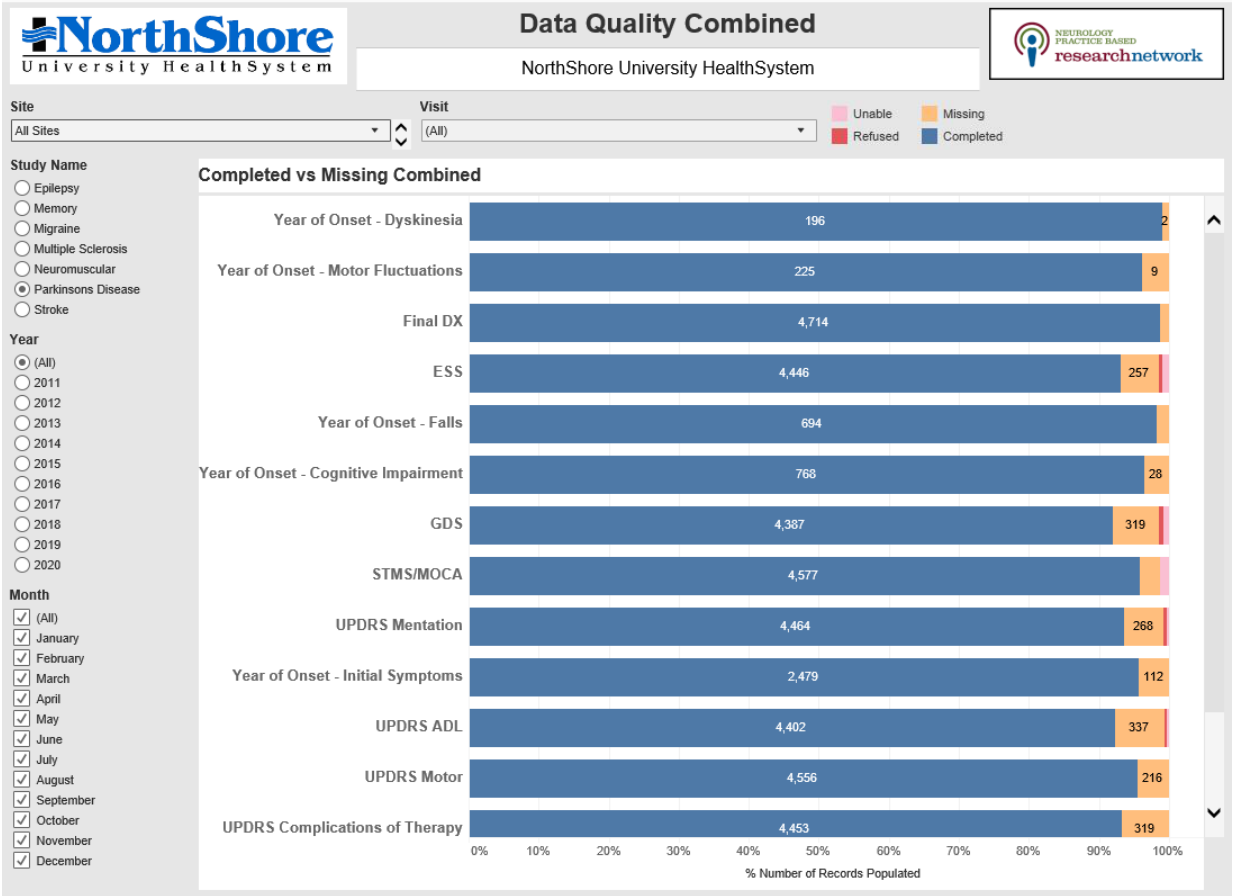


Figure 7F. Parkinson's Disease



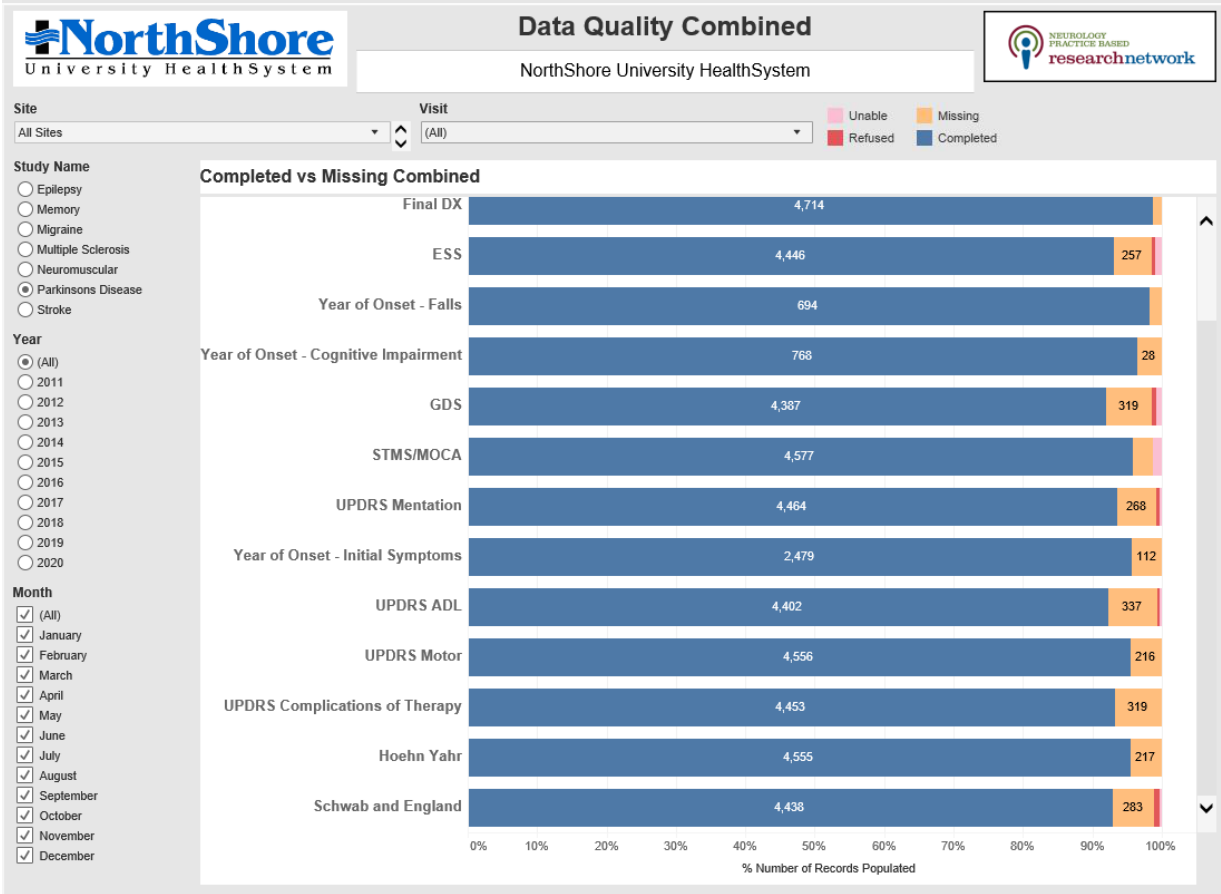
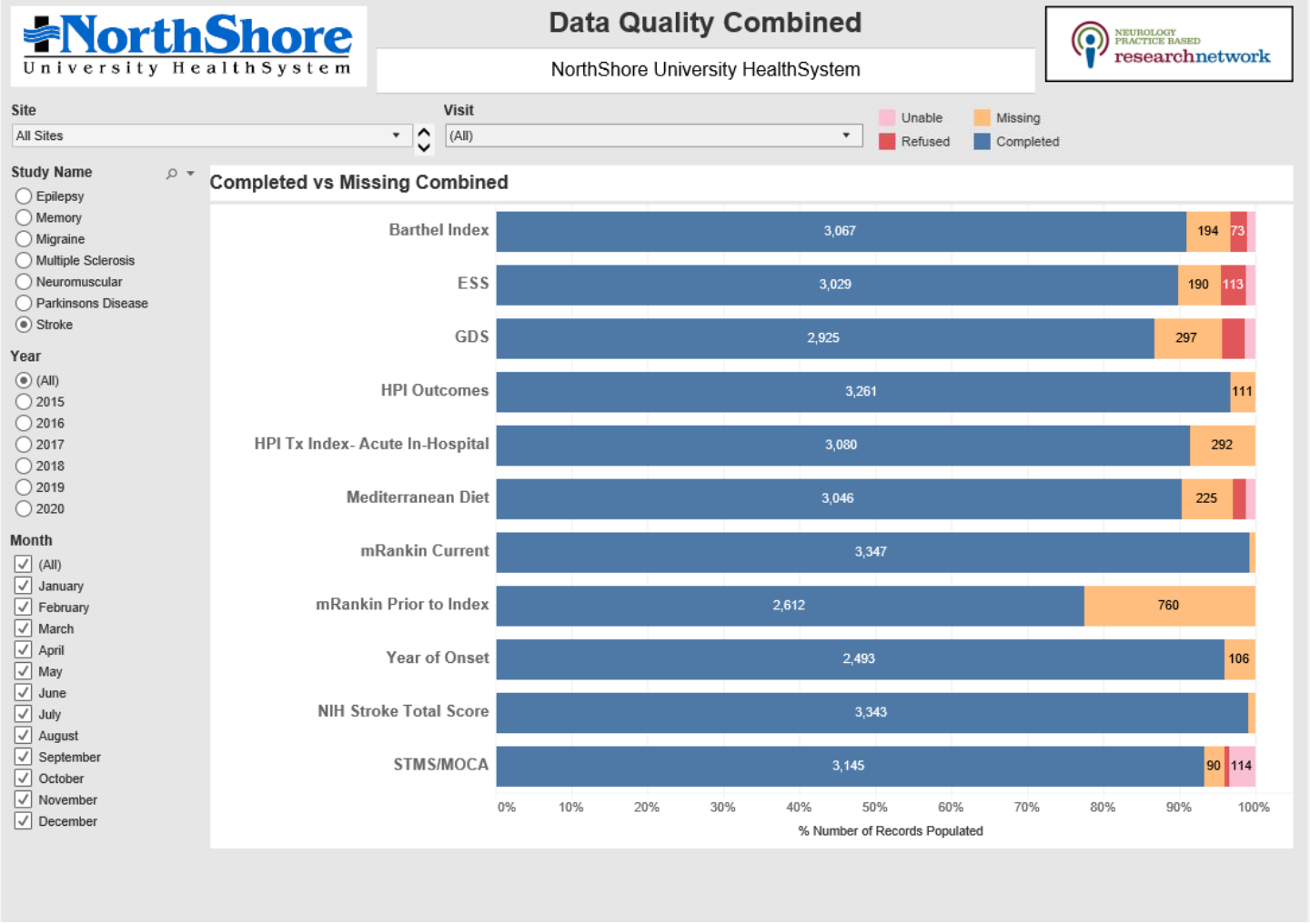


Figure 7G. Stroke



Subgroup-Based Adaptive Design and Pragmatic Trials (Aim 2): For the migraine trial, the enrollment criteria measures included a diagnosis of migraine, migraine frequency (at least 1-3 migraines a month), and no prior use of the compared treatments (amitriptyline, propranolol, topiramate). The three independent variable measures (to guide adaptive assignment) were depression severity (CED-D score), migraine severity (MIDAS score), and presence or absence of aura. The outcome measure was survival free at 6 months of either discontinuation of the assigned drug (due to adverse effects or lack of efficacy) or survival free of an adjunctive/alternative preventive medication.

For the memory trial, the enrollment criteria measures included a diagnosis of mild cognitive impairment, a functional activities questionnaire score <9 (not disabled), and no prior use of the compared treatments (donepezil, rivastigmine, or memantine). The three independent variable measures (to guide adaptive assignment) included the Short Test of Mental Status score, the Geriatric Depression Score, and the type of mild cognitive impairment (amnestic versus other). The outcome measure was survival free at 12 months of disabilities in instrumental activities of daily living (FAQ score of 9+, indicating failure).

For the epilepsy trial, the enrollment criteria measures included a diagnosis of partial epilepsy and no prior use of the compared treatments (carbamazepine, levetiracetam, or zonisamide). The three independent variables (to guide adaptive assignment) included age, the Center for Epidemiological Studies Depression score, and the Short Test of Mental Status score. The outcome measure was survival free at 12 months of discontinuation of the assigned drug or the prescription of an adjunctive therapy.

Limitations: We initially postulated several possible limitations to our study design and methods.

Regarding Aim 1, we cautioned that some of the NPBRN sites would drop out if 1) they were not able to implement our Epic toolkits into their EMRs, 2) the expense of installing and maintaining the toolkits exceeded expectations, 3) they were not able to engage their clinicians in the use of the tools, or if they did not have adequate support from other clinical personnel, or 4) they were not able to share data captured by the Epic toolkits. We also cautioned that there would be delays in implementing the study at some NPRBN sites for a host of reasons. All five limitations, as postulated, were encountered; however, whereas we originally were funded with eight NPBRN sites total, we were able to complete the study with 13 sites (overcoming to some extent the anticipated limitations).

Regarding Aim 2, we cautioned that 1) we may not be able to enroll 300 patients into each of the pragmatic trials, 2) the neurologists would override the adaptive assignments made in silico, 3) the patients would override the adaptive assignments made in silico, 4) we might fail to integrate SUBA software with the Epic software or to output patient-specific data and input patient-specific assignments in real time, or 5) the NorthShore IRB would not exempt pragmatic trials using the EMR from informed consent and that this would impede enrollment at the point of care. Only some of these limitations, as postulated, were encountered. We were able to complete enrollment in our migraine and memory trials, but epilepsy is ongoing. We did encounter a small degree of overriding of adaptive assignments by either the neurologists or patients, but this was effectively managed by sharing with the providers their individual performance data for the trials and by discussing the trials as user group teams every 2 months. Fortunately, we had no difficulty integrating SUBA in the Epic EMR, and the NorthShore IRB approved our enrollment at the point of care as designed.

F. Results

Principal Findings: We published several papers in peer-reviewed journals describing our EMR toolkits for several neurological indications (Aim 1) and also describing our pragmatic trials using the EMR and SUBA (Aim 2). Our initial paper, which provided an overview of our quality improvement and practice-based research initiative using the EMR, was heralded by the Editors of Neurology Today (the official news magazine of the American Academy of Neurology) as one of the Best Advanced for the entire field of Neurology in 2015.

Regarding Aim 1: We were able to grow the NPBRN from eight sites originally to 13 sites. We were able to share EMR toolkits from the primary performance site (NorthShore) to 10 of the partner sites. The University of Connecticut dropped out after license agreements, data use agreements, and IRB approvals were obtained due to a loss of physicians' interest, an the University of Virginia dropped out before the administrative requirements were completed (for similar reasons). The remaining partner sites implemented eight of the 11 EMR toolkits; no site selected the brain health, brain tumor, or sleep disorders toolkits. Most partner sites implemented only a few toolkits (a minimum of two toolkits per site was a requirement for participation). Apart from NorthShore, the primary performance site that implemented all 11 EMR toolkits, the site that implemented the second most toolkits (n=6) was St. Luke's Health System. Unfortunately, the usage of the implemented toolkits at the partner sites was limited, with NorthShore contributing about 90% of the cases to the registry overall and for most toolkits. Most sites reduced or stopped using the toolkits over time. Some of the factors contributing to attrition included the departure of physician leaders or key faculty, lack of consensus regarding the composition of the EMR toolkits (or the time required to complete the required forms, or the staffing requirements), competing registries (e.g., from subspecialty societies), a decline in health information technology support, difficulties implementing new toolkits or upgrades due to Epic version differences between sites, and difficulties logging into the NPBRN registry due to security constraints. The limited participation of partner sites impeded the ability to perform quality improvement projects and outcomes-based research studies. Accordingly, it was decided to not pursue renewal of the grant application. However, one quality improvement project relating to driving safety in patients with memory disorders will be ongoing.

Figure 8 below summarizes the total sample size and demographics for the cases entered into the registry for all sites combined as well as the diagnoses entered. **Figure 9** illustrates time trends for the two visit types (initial and annual follow-up visits).

Figure 8.

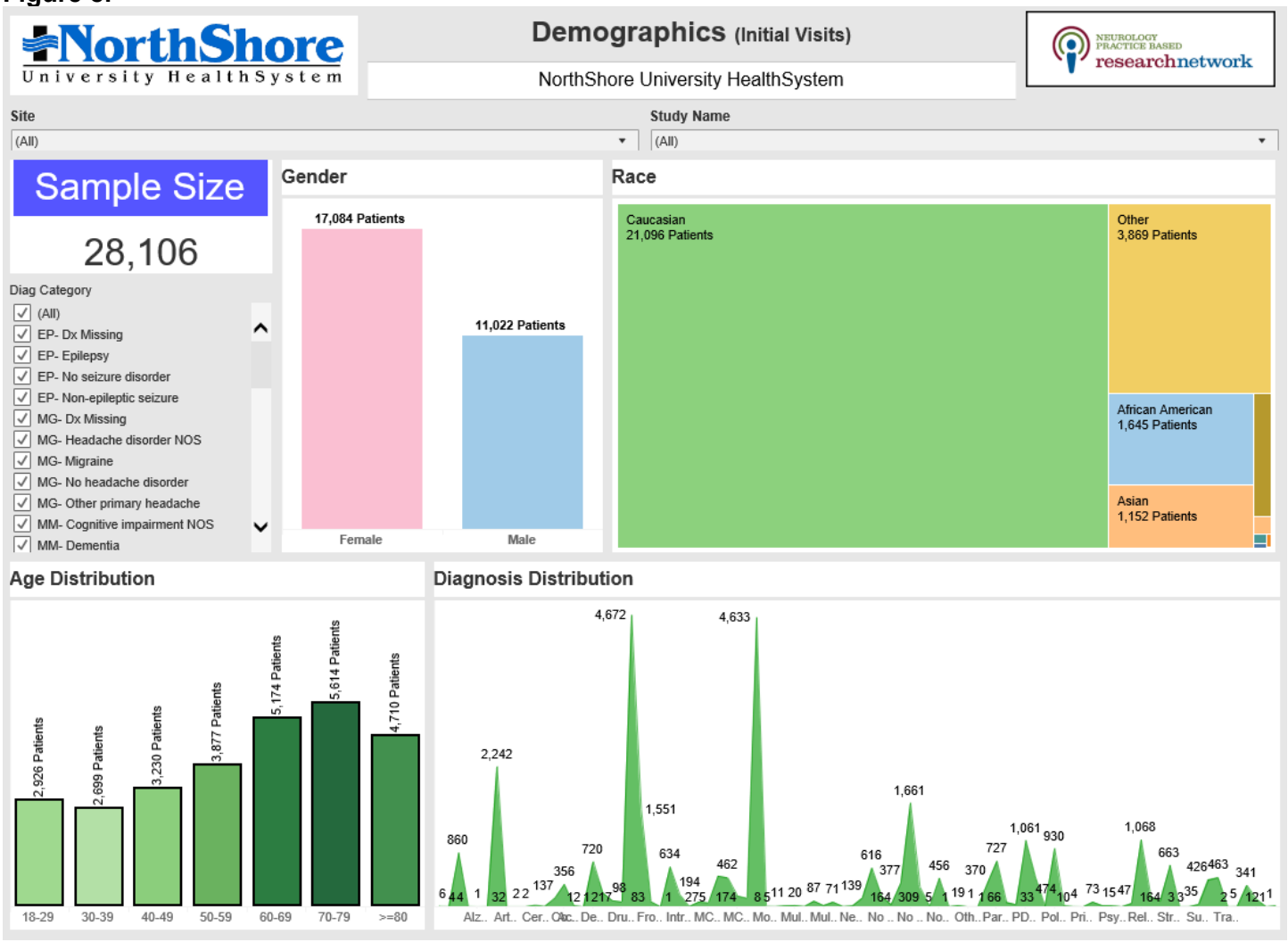
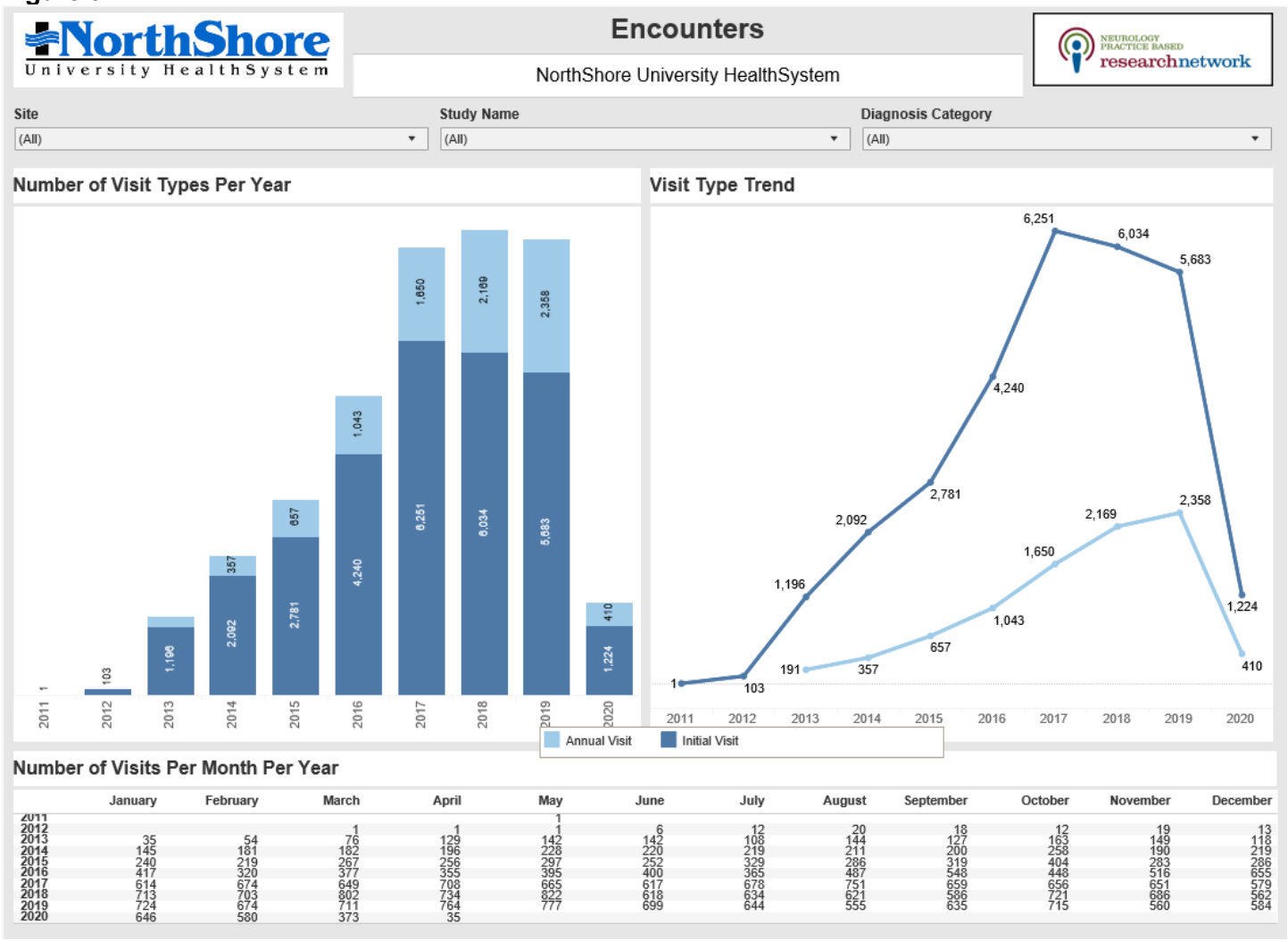

NorthShore University HealthSystem
Demographics (Initial Visits)
NorthShore University HealthSystem
NEUROLOGY PRACTICE BASED researchnetwork
Site
(All)
Study Name
(All)
Sample Size
28,106
Diag Category
(All)
EP- Dx Missing
EP- Epilepsy
EP- No seizure disorder
EP- Non-epileptic seizure
MG- Dx Missing
MG- Headache disorder NOS
MG- Migraine
MG- No headache disorder
MG- Other primary headache
MM- Cognitive impairment NOS
MM- Dementia
Gender
17,084 Patients
11,022 Patients
Female
Male
Race
Caucasian
21,096 Patients
Other
3,869 Patients
African American
1,645 Patients
Asian
1,152 Patients
Age Distribution
2,926 Patients
2,699 Patients
3,230 Patients
3,877 Patients
5,174 Patients
5,614 Patients
4,710 Patients
18-29
30-39
40-49
50-59
60-69
70-79
>=80
Diagnosis Distribution

Figure 9.



	January	February	March	April	May	June	July	August	September	October	November	December
2011					1							
2012			1	1	1	6	12	20	18	12	19	13
2013	35	54	76	129	142	142	108	144	127	163	149	118
2014	145	181	182	196	228	220	219	211	200	258	190	219
2015	240	219	267	256	297	252	329	286	319	404	283	286
2016	417	320	377	355	395	400	365	487	548	448	516	655
2017	614	674	649	708	665	617	678	751	659	656	651	579
2018	713	703	802	734	822	618	634	621	586	721	686	562
2019	724	674	711	764	777	699	644	555	635	715	560	584
2020	646	580	373	35								

Regarding Aim 2: We were able to fully implement into the EMR all aspects of our study design and methods for pragmatic trials using the EMR and SUBA. We were able to effectively alert neurologists of eligible patients randomly and then adaptively assign compared treatments and verbally consent patients using a Best Practice Advisory pop-up at the point of care. We were able to enroll our targeted number of subjects in the migraine trial, and we have captured nearly 300 patient outcomes. Some initial programming errors in treatment assignments were resolved. We are in the process of conducting the final analyses for that study and anticipate submitting a paper with the results for peer-reviewed publication. Our enrollment in the mild cognitive impairment trial was slower than for the migraine trial, as initially only two but ultimately only one physician participated. The outcomes were measured by design at 12 months rather than at 6 months (by contrast to the migraine trial). Nevertheless, we anticipate completion of the mild cognitive impairment trial also in the coming year and plan to analyze those data and publish the results as well. Unfortunately, the vast majority of partial epilepsy patients who we encountered in our clinical practice at the NorthShore site were already assigned to one of the treatments that we wished to compare (typically, levetiracetam). Therefore, we do not anticipate reaching our enrollment targets, and that study will be closed. Although it may have been an option to attempt replication of our migraine trial or our mild cognitive impairment trial at the other participating sites, because usage of the required EMR toolkits was generally low, it was decided to not pursue renewal of the grant application.

Figure 10 below provides enrollment and inclusion information for subjects enrolled in either of the three pragmatic clinical trials.

Figure 10.

PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001
Expiration Date:**03/31/2020**

***Study Title (must be unique):** Quality Improvement and Practice Based Research in Neurology Using the EMR

* Delayed Onset Study? ☐ Yes ☒ No

If study is not delayed onset, the following selections are required:

Enrollment Type	☐ Planned	☒ Cumulative (Actual)		
Using an Existing Dataset or Resource	☒ Yes	☐ No		
Enrollment Location	☒ Domestic	☐ Foreign		
Clinical Trial	☒ Yes	☐ No	**NIH-Defined Phase III Clinical Trial**	☐ Yes ☒ No

Comments: For Aim 1 there is no planned enrollment (observational study only). For Aim 2 there is planned enrollment 300 neurology cases per trial. In the response to the summary statements we agreed to limit the number of pragmatic trials from 10, to three or more. As we will enroll a minimum of 300 subjects per trial, the new planned enrollment will be adjusted to 900 Neurology cases.

Racial Categories	**Ethnic Categories**									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			**Total**
	Female	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	19	8	0	0	0	0	0	0	0	27
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	22	4	0	0	0	0	0	0	0	26
White	256	100	0	2	0	0	1	0	0	359
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	17	4	0	34	8	0	3	0	0	66
Total	314	116	0	36	8	0	4	0	0	478

Figure 11 indicates, for every occasion that the enrollment BPA fired, the action taken by the physician, the number of patients enrolled, and the participation rates by study and overall.

Figure 11.

Study	Selected Options in Response to the BPA	Enrollments	Withdrawals	BPA Fires	Enrollment Rate
Epilepsy	Assign Medication Non-Adaptively	0	0	2	
	BPA In Error	0	0	2	
	Contraindication to Medication	0	0	4	
	Defer Assignment (Medication Not Indicated)	0	0	3	
	Enroll Patient	19	0	19	
	'Enroll Patient' Selected in Error	0	0	1	
	Optimize Current Medication	0	0	17	
	Other (Comment)	0	0	9	
	Patient/Family Refusal	0	0	11	
	Physician Prefers Other Medication	0	0	4	
Epilepsy - Summary		**19**	**0**	**72**	**26.4%**
Memory	BPA In Error	0	0	2	
	Contraindication to Medication	0	0	16	
	Defer Assignment (Medication Not Indicated)	0	0	28	
	Enroll Patient	136	6	138	
	Optimize Current Medication	0	0	3	
	Other (Comment)	0	0	6	
	Patient/Family Refusal	0	0	32	
	Physician Prefers Other Medication	0	0	15	
Memory - Summary		**136**	**6**	**240**	**56.7%**
Migraine	Assign Medication Non-Adaptively	0	0	3	
	BPA In Error	0	0	22	
	Contraindication to Medication	0	0	76	
	Defer Assignment (Medication Not Indicated)	0	0	208	
	Enroll Patient	323	82	323	
	'Enroll Patient' Selected in Error	0	0	14	
	Optimize Current Medication	0	0	20	
	Other (Comment)	0	0	64	
	Patient/Family Refusal	0	0	280	
	Physician Prefers Other Medication	0	0	76	
Migraine - Summary		**323**	**82**	**1,086**	**29.7%**
Overall - Summary		**478**	**88**	**1,398**	**34.2%**

Outcomes: With respect to Aim 1, because of a limited number of actively participating NPBRN sites, using a limited number of toolkits per site, and with a low number of patients contributed to the registry (apart from the primary performance site), we do not plan to renew the grant. Whether the primary performance site (NorthShore) will maintain the registry or not, and whether the remaining participating sites will continue to contribute data, will be determined in the coming months by the respective parties. We are planning to write a paper summarizing the experiences of the NPBRN, include pitfalls and lessons learned, for publication in a peer-reviewed journal. We hope that our paper will inform the design of future quality improvement and practice-based research initiatives in neurology using the EMR.

With respect to Aim 2, we anticipate completing our migraine trial and our mild cognitive impairment trials in the coming 12 months and submitting our findings for publication in peer-reviewed journals. Because of low enrollment, we do not anticipate completing the epilepsy trial. Though it may have been an option to replicate our findings for migraine and mild cognitive impairment in a multicenter trial, because of low usage of the EMR toolkits required for the study at the other sites, we do not anticipate renewing the grant for this purpose either.

Figure 12 below summarizes for each of the three pragmatic trials, the outcomes of the assigned treatments as captured by the EMR (Failure = the assigned treatment failed, Success = the assigned treatment succeed, Pending = the assigned treatment outcome is pending). Until at least 300 outcomes are captured for each trial separately, SUBA will not be able to provide a final assessment as to how the assigned treatments compared.

Figure 12.

PRAGMATIC TRIAL	EMR OUTCOMES	COUNTS
Epilepsy	Failure	**9**
	Success	**8**
	Pending	**2**
	Summary	**19**
Mild Cognitive Impairment	Failure	**21**
	Success	**56**
	Pending	**2**
	Summary	**79**
Migraine	Failure	**67**
	Success	**146**
	Pending	**15**
	Summary	**228**
Summary		**326**

Discussion: With respect to our first aim, there are many theoretical benefits to the use of SCDS and CDS toolkits for the evaluation and management of neurological disorders. Structured EMRs: 1) standardize clinicians to Best Practices; 2) reduce variability (creating efficiency); 3) navigate care within a team of providers; 4) capture data in real time (in support of quality improvement and practice-based research); 5) provide clinical decision support (in support of patient safety, quality, and precision medicine); 6) support note writing, billing compliance and reimbursement, pay for performance, and timely communications with patients and referring physicians; 7) define and collect process and outcome measures as required for improving quality and creating a learning health system; 8) educate medical students, residents, and fellows to Best Practices; 9) support practice based research (including pragmatic trials and biobanking); 10) support scholarly productivity, which in turn creates professional satisfaction and may mitigate burnout; 11) differentiate clinical practices in the competitive marketplace (promoting practice growth); 12) create opportunities for national leadership (e.g., registries, networks); and culminate in medical discovery and innovation of Next Practices. At the NorthShore primary performance site, we were able to demonstrate all of these benefits. Unfortunately, we were not able to replicate that experience across the NPBRN, in part due to a lack of physician engagement (behavioral barriers), a lack of health information technology and staff support (resource barriers), and EMR version incompatibilities and failed registry logins (technical barriers). With respect to our second aim, we demonstrated the feasibility of pragmatic clinical trials using the EMR and SUBA. We anticipate the results from two of our three trials soon. However, limited use of the EMR toolkits across the NPBRN sites will preclude efforts to replicate our findings using the same study design.

We propose that future initiatives to improve quality in neurology and to support practice-based research should be EMR platform agnostic. The construction and maintenance of limited data set registries should be led by professional organizations, such as the American Academy of Neurology, which are dedicated to the provision of evidence-based clinical practice guidelines and to the improvement of the quality of care.

Conclusions: We succeeded in sharing several EMR toolkits with many NPBRN sites and in creating a data registry. We succeeded in the implementation and conduct of pragmatic clinical trials using the EMR and adaptive designs. Unfortunately, there were several barriers to full participation in our studies, limiting the scope of these quality improvement and practice-based research initiatives.

Significance: We have identified pitfalls and lessons learned with respect to quality improvement and practice-based research in neurology using the EMR.

Implications: We will disseminate our learnings regarding quality improvement and practice-based research in neurology using the EMR toward the design of more successful initiatives in the future.

G. List of Publications and Products

Quality improvement and practice-based research in neurology using the electronic medical record. Maraganore DM, Frigerio R, Kazmi N, Meyers SL, Sefa M, Walters SA, Silverstein JC. Neurol Clin Pract. 2015 Oct;5(5):419-429. PMID: 26576324

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Use of an Electronic Medical Record to Track Adherence to the Mediterranean Diet in a US Neurology Clinical Practice. Rasmussen E, Fosnacht Morgan AM, Munson R, Ong A, Patel S, Yucus C, Pham A, Patel V, Frigerio R, Lai R, Hillman L, Tideman S, Wang C, Simon KC, Martínez-González MÁ, Maraganore DM. Mayo Clin Proc Innov Qual Outcomes. 2018 Feb 1;2(1):49-59. doi: 10.1016/j.mayocpiqo.2017.12.003. eCollection 2018 Mar. PMID: 30225432

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Design and Implementation of Structured Clinical Documentation Support Tools for Treating Stroke Patients. Simon KC, Munson R, Ong A, Gil FR, Campanella F, Hillman L, Lai R, Chesis R, Tideman S, Vazquez RM, Meyers S, Frigerio R, Maraganore D. J Stroke Cerebrovasc Dis. 2019 Feb 5. pii: S1052-3057(19)30011-4. doi: 10.1016/j.jstrokecerebrovasdis.2019.01.011. PMID: 30737069

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