Research Article

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Development of an Integrated Multiple Sclerosis Flowsheet Registry to Bridge the Gap between Electronic Health Record Functionality and Clinical Information Needs

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Received: November 12, 2015; Accepted: December 25, 2015; Published: December 27, 2015

Abstract

We describe development of the Integrated Multiple Sclerosis (MS) Flowsheet Registry to provide a longitudinal, complete clinical picture of the MS patient for clinical care decision making, insurance authorizations, and research at the INI MS Center in downstate Illinois. The MS Flowsheet concept was envisioned in 2009 and has transformed from a paper version to an MS specific registry capable of interacting with their EHR. A decision was made to develop a research protocol to study the cost benefit of integrating the MS Flowsheet Registry into practice as a collaboration between OSF Saint Francis Medical Center, INI MS Center, and UICOM-P. The MS Flowsheet Registry described was implemented as part of this research project. Advantages to implementing the registry include: providing a one cohesive mechanism for the provider and staff to view each MS patient's individual MS profile, streamlining the prior authorization process for DMT approval thereby expediting DMT access to decrease relapse rates and progression, and increasing research opportunities at the local level. The primary disadvantage of the registry is that it is a work around solution and only a temporary fix as improved EHR capabilities are considered for future purchase. We expect that the MS Flowsheet Registry will result in improved patient care and cost savings and additional studies are needed to evaluate the cost benefit

Keywords: Registries; Database Management Systems; Electronic Health Records; Decision Support Systems; Multiple Sclerosis

Abbreviations

9HPT: 9 Hole Peg Test; DMT: Disease Modifying Therapy; EHR: Electronic Health Record; EDW: Enterprise Data Warehouse; EDSS: Expanded Disability Status Scale; INI: Illinois Neurological Institute; IDEA: Instant Data Entry Application; MOA: Medical Office Assistant; MS: Multiple Sclerosis; PPMS: Primary Progressive Multiple Sclerosis ; PRO: Patient Reported Outcomes; RRMS: Relapsing Remitting Multiple Sclerosis; SPMS: Secondary Progressive Multiple Sclerosis; T25FW: Timed 25 Foot Walk; US: United States; UICOM-P: University of Illinois College of Medicine Peoria

Introduction

This paper describes the development of the Integrated Multiple Sclerosis (MS) Flowsheet Registry at the Illinois Neurological Institute (INI) Multiple Sclerosis Center. The promise of information technology solutions to improve health care is seldom realized [1], and the gap between health information system design and reality persists [2]. This was the case at the INI MS Center after system-wide implementation of a commercially available electronic health record (EHR).

An estimated 400,000 people in the United States (US) are

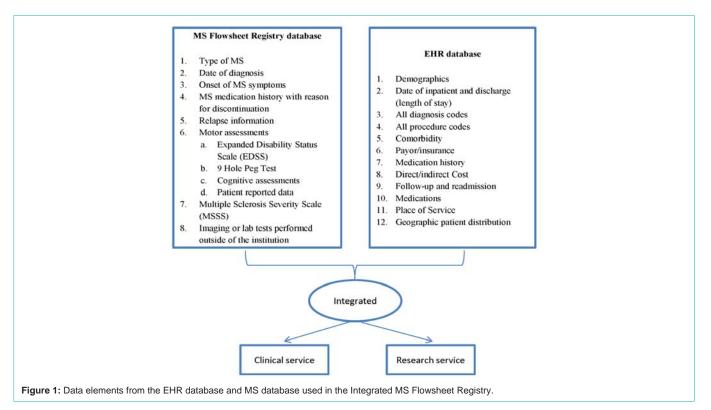
diagnosed with MS [3], with incidence rate affected by sunlight exposure, gender, age, and ethnicity [4]. Initial symptoms appear between the ages of 20 and 40 years, impacting productivity, employment, and quality of life [5]. MS is included in the World Health Organization top 100 diseases affecting quality of life [5], and we spend 445 million USD on direct MS care annually [6]. However, annual indirect costs exceed 10 billion USD [4,7]. The clinical course of MS often differs among individuals and symptoms can vary [8,9]. Tracking long-term patient outcomes in the real-world clinical setting could help physicians and researchers understand this disease better.

In fact, the EDMUS European MS registry has been in use for more than 20 years [10,11], and standalone databases to support the care of MS patients is not new [12-14]. However, during the push to adopt EHRs, many specialty databases fell by the wayside. Much of the data about the course of MS progression is present in the EHR narrative progress notes or "buried" within visit encounters only. The Veterans Health Administration has had success with extracting data on MS from its EHR to support patient care [15], and natural language processing algorithms show promise with extracting MS data from commercially available EHRs [16,17]. However, not every organization has the same capabilities for automated data extraction, and manual chart review is time-consuming.

Austin J Mult Scler & Neuroimmunol - Volume 2 Issue 4 - 2015 **Submit your Manuscript** | www.austinpublishinggroup.com Cooley et al. © All rights are reserved

Citation: Cooley KL, Paris BL, Asche CV and Valenzuela R. Development of an Integrated Multiple Sclerosis Flowsheet Registry to Bridge the Gap between Electronic Health Record Functionality and Clinical Information Needs. Austin J Mult Scler & Neuroimmunol. 2015; 2(4): 1023. Cooley KL

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OSF Saint Francis Medical Center, INI and the Center for Outcomes Research at University of Illinois College of Medicine at Peoria collaborated on development of the MS Flowsheet Registry, which has the potential to provide outcome data in reportable format, support future research projects, and contribute healthcare cost savings. In addition, the insurance authorization process for disease modifying therapy can be iterative and lengthy, resulting in rework for nursing staff and delays in treatment for patients. Perhaps more importantly, the MS Flowsheet Registry will provide a full picture about each patient's individual MS course. This information can facilitate discussion and understanding between the patients and care providers.

Materials and Methods

Each year, over 600 MS patients are treated at INI MS Center, the only MS Center located in downstate Illinois. In late 2009, a research coordinator (KC) envisioned an MS Flowsheet Registry to support patient care and research. At that time, the clinic was using paper based charting. The research coordinator worked with the providers, nursing staff, and manager to determine what information needed to be captured on a one-page sheet. A paper flowsheet was created and filed in the hard chart behind its own tab labeled: MS Flowsheet.

In 2010, implementation of an EHR in 2011 was announced, and it was hoped that the MS Flowsheet data could be captured within this new EHR. The new EHR, EPIC, went into production at the clinic in August 2011. Although the EHR has greatly improved dissemination of healthcare data among disciplines, the MS Clinic saw a gap in regards to data extraction for outcome reporting with the MS population. In the EHR, specific MS information was documented in narrative format only; this information included: type of MS, date of diagnosis, onset of MS symptoms, MS medication history with reason for discontinuation, relapse information, motor assessments including: Expanded Disability Status Scale (EDSS), Timed 25 Foot Walk (T25FW), 9 Hole Peg Test (9HPT), cognitive assessments and any patient reported outcome (PRO) questionnaires. In addition, any imaging or lab tests performed outside of the institution could not be extracted electronically since those paper reports were scanned into the EHR.

Over time it became cumbersome to search through multiple encounters to review the MS patient's individual clinical course. For example, there was nowhere to see how the T25FW progressed over time for a given patient. Disease modifying treatment (DMT) review was also difficult. The medication start date documented in the EHR was actually the date of the last time the medication was ordered by the provider, not the date the patient actually initiated the medication. Other key information such as date of MS diagnosis, date of first onset of MS symptoms, start and stop dates of previous DMT prescriptions, and reason for DMT discontinuation was not in an easily extractable format. Manual chart review was needed to complete insurance authorizations and to support MS clinical trials. MS data needed to be reportable whenever an outcome was queried. Purchasing additional software was not an immediate option, so an alternative was investigated.

In 2012, the research coordinator, clinic manager, nursing staff, and providers from the MS Clinic began to work with outcomes researchers at a local college of medicine to collaborate and address these issues. The concept of an integrated MS Flowsheet Registry was developed, combining data elements from the EHR database and a new MS Registry based off of the paper flowsheet. Affiliated with OSF Healthcare System, this clinic predicted the benefits to patient

Cooley KL

Table 1: MS Flowsheet Registry Clinic Data Entry Process.

Event Triggering Data Entry	Performed By	Activity Description
New MS Patient Identified	Assistant	Assistant reviews the EHR after a new patient encounter. If a MS diagnosis is confirmed, complete history is added in Registry. If MS diagnosis is not confirmed, the assistant makes note of their next visit date so follow-up after the appt. occurs. If MS diagnosis is confirmed at a follow-up, complete history is added in Registry.
Existing MS Patient has an appointment within 1 week	Assistant	Assistant confirms if the patient has been added to Registry. If no, complete MS history is added in Registry. If yes, the EHR is reviewed since the last appointment and the Registry updated if needed (i.e. new labs, relapse info, MRI, change in DMT). Assistant consults RN or MD with questions.
	Assistant	MOA rooms patient. T25FW and 9HPT are performed. T25FW and 9HPT scores are entered in the Registry. Other clinical data entered in EHR
MS Patient Appointment	Provider	Registry reviewed prior to examining patient. Provider fills in missing data if applicable (Type of MS: RRMS, SPMS, PPMS, etc.)
	Nurse	Confirm with MD the plan of care during patient discharge. Update Registry if applicable (i.e. DMT change, steroids ordered for relapse, vitamin D dose change) NOTE - Many updates won't happen until after testing is complete (MRI / labs) or after insurance approval for a new DMT
MS Patient calls clinic (telephone encounters)	Nurse	Registry will be updated during patient phone encounters (i.e. DMT updates, relapse orders)
MS Patient test results received	Nurse	Registry will be updated after the provider acknowledges or gives further instruction: Labs captured in the database (serum vitamin D, JCV ab and index level, NMO, etc.) MRI's (brain or spine) CSF results

Abbreviations: MOA: Medical Office Assistant; DMT: Disease Modifying Therapy; PPMS: Primary Progressive Multiple Sclerosis; RRMS: Relapsing Remitting Multiple Sclerosis; SPMS (Secondary Progressive Multiple Sclerosis); T25FW: Timed 25 Foot Walk Test; 9HPT: Nine-hole peg Test Table 2: Advantages and Disadvantages of integrating a MS Flowsheet Registry with an EHR.

Advantages	Disadvantages
One cohesive mechanism for the provider to review each individual MS patient's entire clinical	It is a "work around" or temporary fix for a gap that exists with the
profile.	current EHR.
Assists MS nurses and staff as they proactively provide information for prior authorizations.	"Real time" outcome reporting not possible. (There is at least a one
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Expedites disease modifying therapy start dates for patients, which will positively affect a	Could be viewed as duplicate data entry. (Some of the information
decrease of relapse rates and disability progression.	entered is available in narrative format within the EHR.)
Provides an avenue to generate outcome reports. [This is important information to have at their	Multiple staff resources needed for its success to materialize.
fingertips since OSF Saint Francis Medical Center is an Accountable Care Organization (ACO)].	
Promotes investigator-initiated research opportunities on their local MS population.	Once the Registry has gone into production, certain updates cannot
	be made.
Improves potential for grant acceptance by delivering accurate and comprehensive data on the	Cannot sort entries by date chronological order.
MS population served at the clinic.	, , ,
Assists in providing information required of sponsored clinical trials in a comprehensive and	Deleting cases accidentally is possible. (IT back-ups will enable
intuitive manner.	retrieval of deleted cases should this happen).

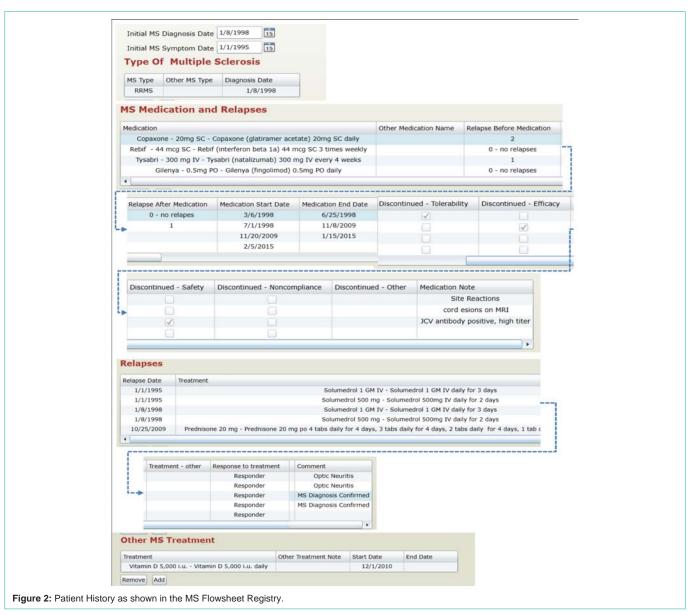
care, staff satisfaction, research and cost savings if an MS Registry was integrated within the EHR. Please refer to Figure 1 for the data elements and vision of the team.

Results and Discussion

Although it was technically feasible to modify the EHR to address the information needs of the MS Clinic that was not a practical option given organizational resources. The OSF Data Analytics department suggested using Instant Data Entry Application (IDEA) software to develop a customized solution integrated with the EHR, as both EPIC and IDEA interface with the Enterprise Data Warehouse (EDW), which would enable outcome reporting. We developed a research study to examine the cost benefit of integrating the MS Flowsheet Registry with the current EHR, and Data Analytics worked closely with the research team to create the MS Flowsheet Registry in an electronic format as an IDEA database. The entire clinical picture of the MS patient could then be viewed by providers to support patient care.

The INI MS Center is in the early stages of adopting this change within their daily practice. Research assistants were hired to enter data, and a research coordinator performed quality checks to ensure accuracy. On average, it took 1 hour per patient to extract historical data from the medical record (EHR and paper charts). How long this process took relied heavily upon how long ago the patient had been coming to the clinic and whether paper charts existed for that patient. More complex disease course took longer to extract, and assigning dedicated research assistants to this duty helped lesson the burden at the clinic for extracting the initial registry data. Refer to Table 1 to review the MS Flowsheet Registry Clinic Process.

Advantages and challenges of using the MS Flowsheet Registry in clinical practice are reflected in Table 2. In the years prior to the implementation of the registry, tracking data was accomplished through manual practices: the research coordinator maintained a "patient watch list" in Excel to identify eligible participants for clinical research trials and manually reviewed patient records. Clinic staff performed manual chart reviews each time a prior authorization or clinical care question arose. Providers reviewed past encounters in the EHR prior to examining patients, trying to piece together the patient's current clinical picture. We predict that the MS Flowsheet Registry will reduce time spent on chart review, allowing providers and nurses to spend more time with patients. For example, staff will be able to view the complete MS history of the patient directly



within the Registry to answer prior authorization queries and to help facilitate patient care decisions at visit encounters. Also, reports will be generated to streamline the process of prescreening records to identify potential clinical trial participants. Refer to Figures 2, 3, and 4 for screenshots of the MS Flowsheet Registry. Demographic information is not shown, and data provided is for example purposes only.

The main challenge with integrating the MS Flowsheet Registry and EHR at the clinic has been retrospective data collection on exisiting MS patients. The approach we used was a simultaneous "go live" and retrospective data collection. It is not unusual for patient appointments to be added last minute, and this has caused instances where there was not sufficient time for the assistants to enter past information in the Flowsheet Registry before the provider saw the patient. Providers and staff at the INI MS Clinic have worked through the challenges of registry implementation, focusing on the benefit to patient care. Over time, all patients will be entered and a dedicated person will take ownership of the MS Flowsheet Registry to ensure it is kept up to date by all staff. For future registry projects, we recommend a separate retrospective data collection phase from the production phase.

Many of the issues faced by the INI MS Center are not unique to treatment of MS in particular but are related to the complexity of treating patients with multiple chronic conditions [18]. Comorbidities among MS patients complicate management. Cost of illness is higher, and health-related quality of life is lower for MS patients with impaired mobility [7], which is affected by comorbid conditions [19,20]. The prevalence of comorbid conditions with MS is high; 37% of patients with MS had at least one physical comorbidity [21] and 48% of patients with MS had at least one mental comorbidity [22]. Adverse health factors such as smoking and obesity are also common [20,21,23,24]. These comorbidities and lifestyle factors may affect the delay between symptom onset and diagnosis, disability progression, and health related quality of life [19,21,23,24].

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Figure 3: Testing Results as shown in the MS Flowsheet Registry.

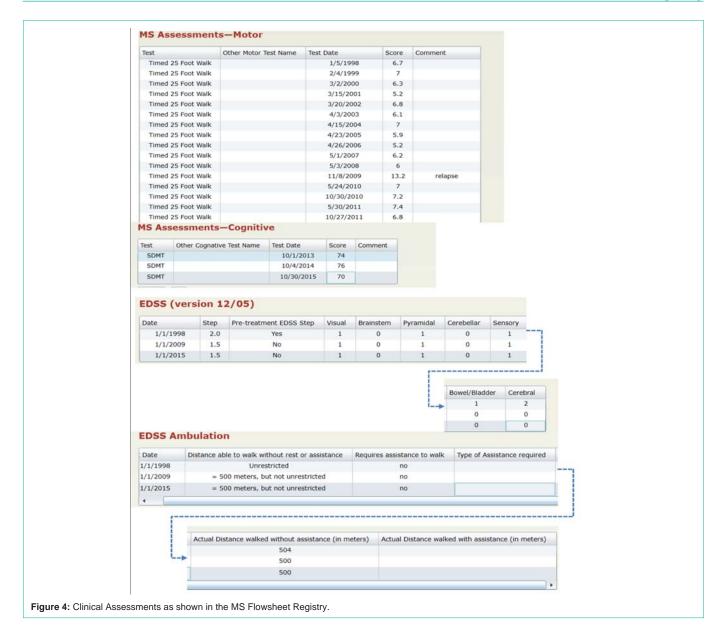
Comorbidities in MS adds to complexity of managing the disease, but management is also complicated by EHRs that do not meet the needs of healthcare providers, leading to workarounds [25]. Workflow and EHR information flow are not necessarily aligned, and specialty clinics are seldom involved in development of IT solutions [26]. This project is an exception because development of the solution was led by clinicians. However, this project could also be viewed as a computer-based workaround involving development of a registry and integration with the existing EHR. The MS Flowsheet Registry allows us to capture data on our MS patients immediately, and results of the research study will inform future software development or purchase.

Conclusion

We expect that the MS Flowsheet Registry will result in improved patient care and cost savings due to providing a longitudinal, complete clinical picture of the MS patient for clinical care decision making, insurance authorizations, and research. Additional studies are needed to evaluate the cost benefit of integrating a patient database within an EHR for the management of MS. Future research could focus on other specialty practices within the OSF Healthcare System, such as other neurology sub-types (stroke, muscular dystrophy, epilepsy, etc.) or other specialty practices (cardiology, rheumatology, pulmonology) and the creation of more specialty patient databases integrated with the EHR.

Acknowledgment

The authors would like to acknowledge Sarah Clark, MSN, RN, CCRC, Patrick Elwood, MD, Dennis Garwacki, MD, Linda Gonia, MPA, Kimberly Shafer Haddock, RN, CPN, CCRC, Noreen Khan, MD, Jorge Kattah, MD, Annie McClure, BS, Phil Oelker, BS, Jessica Svendsen, BA, CCRC, Larry Wallden, and Kim Wankel for their contributions to this effort. A special thanks to the staff and leadership in the Clinical Research Department at OSF Saint Francis Medical Center and at the INI MS Center. We would like to thank



the Central Illinois MS Council for funding this research. The Central Illinois MS Council & MS Clinic Fund is a not-for-profit volunteer organization dedicated to transforming healthcare for MS patients and their families in Central Illinois.

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