Healthcare Transformation with Informatics and Artificial Intelligence
J. Mantas et al. (Eds.)

doi:10.3233/SHTI230510

Using Redcap to Support the Development of a Learning Healthcare System for Patients with Multiple Sclerosis

m. VIGUERA[a,1], f. MARTIN-SANCHEZ[b] and M.E. MARZO[c]
[a] *U.N.E.D.*
[b] *Instituto de Salud Carlos III*
[c] *Hospital San Pedro*
ORCiD ID: Minerva Viguera https://orcid.org/0009-0006-9286-7171

Abstract. Multiple Sclerosis is a neurodegenerative disease which shows different phenotypes making difficult for clinicians to make short-term decisions related with treatment and prognosis. Diagnosis is usually retrospective. Learning Healthcare Systems (LHS) can support clinical practice as they are devised as constantly improving modules. LHS can identify insights which allow evidence-based clinical decisions and more accurate prognosis. We are developing a LHS with the aim of reducing uncertainty. We are using ReDCAP to collect patients' data, both from Clinical Reported Outcomes (CRO) and from Patients Reported Outcomes (PRO). Once analyzed, this data will serve as a foundation to our LHS. We conducted bibliographical research to select those CRO and PRO collected in clinical practice or identified as possible risk factors. We designed a data collection and management protocol based on using ReDCAP. We are following a cohort of 300 patients for 18 months. At the moment, we have included 93 patients and received 64 complete responses and 1 partial response. This data will be used to develop a LHS, able to accurate prognosis as well as to automatically include new data and improve its algorithm.

Keywords. Multiple sclerosis, Learning health system, Patient-reported outcomes

1. Introduction

A Learning Healthcare System (LHS) can be defined as a clinical tool committed to narrowing the research-practice divide by collecting and analyzing data to generate evidence and support health decisions [1]. The main goal is to close the loop formed by

[1] Corresponding Author, Minerva Viguera. U.N.E.D. Email:m.viguera@externos.isciii.es.

patient's data, Real World Evidence and clinical practice to generate clinical evidence, facilitate evidence-based medicine and personalized clinical decisions [2].

Research Electronic Data Capture (REDCAP) is being used to centralize and manage all data, ensuring anonymization and ethical compliance [3, 4].

Multiple Sclerosis (MS) is a chronic disease that affects the central nervous system with an unpredictable progression. It usually starts with relapses followed by remission but can also develop into a secondary progressive stage. The time interval between MS first manifestations and the onset of the secondary progressive stage varies greatly, with an average period of approximately 20 years [5]. Identifying the secondary progressive stage quickly and accurately is important, as therapeutic alternatives have shown clinical benefits in modifying disease progression [6]. However, progression from relapsing-remitting MS (RRMS) to secondary progressive MS (SPMS) is a continuous process characterized by subtle changes that are often reported by patients but undetectable by neurological exploration [7].

2. Objectives

Our research aimed to evaluate ReDCAP as a tool for collecting patient data from PRO questionnaires, lab test results, and clinical records. Through our experience with ReDCAP, we gained valuable insights into its efficacy and potential for supporting clinical decisions. Additionally, we aimed to identify prognostic factors for disease progression and develop LHS. While these broader aims were important, our focus in this paper is on our experience with ReDCAP and its utility for collecting patient data in a clinical setting.

3. Methods

We conducted bibliographical research to identificate prognosis factors and validated questionnaires. Older age at MS onset, male sex, early high relapse frequency, longer disease duration, higher baseline EDSS score, greater early increase in EDSS score, higher T2 lesion burden, spinal cord involvement, and lower brain volume are risks factors associated with progression in SPMS [6]. An association of self-reported levels of education with disability progression in MS has been shown, associating higher levels as protective in relapsing-onset MS [11].

Based on all these risk factors, we are collecting PRO, CRO and blood analysis for 18 months, using validated questionnaires and clinical tests on a cohort of 300 patient diagnosed with RRMS or SPMS by collecting and analyzing data from CROs (from outpatient consultation within the EHR), PROs, blood tests and specific biomarkers [6]. We centralized all this data through ReDCAP, which allows researchers to create a survey link for each project to provide online access to the questionnaires.

Patients were recruited during outpatient visits at the hospital. Those who expressed interest in participating were provided with a consent form to sign. Once signed, patients were given the link and a QR to access the online survey on REDCap, which consisted of seven questionnaires measuring different aspects of their health and well-being: Five validated questionnaires were selected to evaluate fatigue (FSS questionnaire), general impact (MSIS-29 and MSQoL 54), depression, and cognitive function (neuro-QoL), and anxiety (Haq Index).

Besides, we included an initial questionnaire that required patients to input their assigned number and gender -this allowed us to reduce the number of questions displayed by only showing those related to their gender- and a satisfaction questionnaire. The assigned patient number was critical for tracking responses at different points in time, as well as for correlating responses with the CRO, allowing us to maintain accurate longitudinal data [10]. The satisfaction questionnaire was designed to evaluate the participants' satisfaction with the study and the questionnaire administration process [11].

The Survey Invitation tool was key to contact participants while maintaining anonymity. Specifically, we utilized this tool to send reminders to patients who did not initially respond to the questionnaire, as well as to schedule automatic reminders every three months to facilitate ongoing patient compliance [4].

To capture CRO, both electronic health records and prospective data are being collected. General patient information such as month and year of birth and diagnosis, MS progression form, number of outbreaks, new outbreaks in the last 6 months, EDSS score, 25-foot test, 9 holes, spasticity, cerebral RMN (baseline and subsequent), medullary RMN, number of bounds, and pharmacological treatment were also collected.

4. Results

We conducted bibliographical research to identify risks factors which have demonstrated relation with disease progression. Several PROS have been evaluated. Physical disability and depression at baseline have been identified as significant prognosis factors [10].

Until the date, a total of 93 patients were invited to participate in the study, of which 92 accepted. We have received responses 65 from patients (response rate of 70%)., of which 60 are complete and five are partial. We have reached out to three patients who provided partial responses by mail; two of them have since completed the questionnaires. Other two completed their surveys within one week of their first attempt without any reminder by our side. These results are shown in fig. 1.

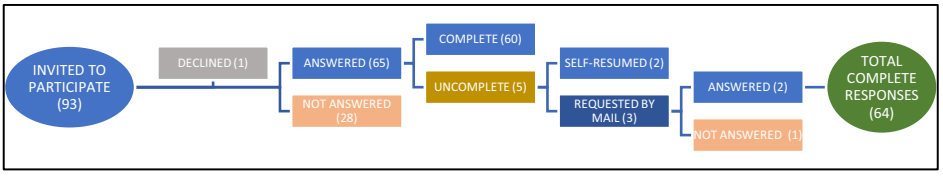

Figure 1. Participation scheme

Based on the 64 responses to our satisfaction questionnaire, most patients were able to answer the questionnaires in a short amount of time. Specifically, 46 patients indicated that it took them less than 30 minutes to complete the questionnaire, while 15 patients reported that it took them between 30 and 60 minutes. Only one patient needed more than an hour to complete the questionnaires.

We also ask about the viability of take the survey every 3 months. Interestingly, six patients also provided feedback about specific questions within the questionnaire. All noted that some questions did not have enough answer options. Upon review, we discovered errors in the translation of the sexual health block, which we were able to quickly rectify. Overall, these results provide valuable insights into patient satisfaction with our questionnaire and highlight areas where we can improve user experience.

5. Discussion

The use of the ReDCAP tool has greatly facilitated the collection of very diverse patient and clinical reported data, capturing important patient-reported outcomes, which provided valuable insights into the impact of MS on patients' capabilities quality of life. Althoug our results are preliminary, REDCap has proved to be a reliable and effective method for capturing PRO data from a large sample of patients over an extended period of time. Our satisfaction questionnaire yielded valuable insights into patient satisfaction, including most patients being able to complete the task in a short amount of time, a high level of agreement with the possibility to answer the questionnaire every three months, and feedback which led to the identification and resolution of translation errors.

References

[1] Olsen L, Aisner D, Mcginnis JM. The Learning Healthcare System: Workshop Summary (IOM Roundtable on Evidence-Based Medicine). 2007 [cited 2021 Nov 24]; Available from: http://www.nap.edu/catalog/11903.html.

[2] Peng J, Jury EC, Dönnes P, Ciurtin C. Machine Learning Techniques for Personalised Medicine Approaches in Immune-Mediated Chronic Inflammatory Diseases: Applications and Challenges. Available from: www.frontiersin.org.

[3] Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)-A metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009 Apr;42(2):377–81.

[4] Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform. 2019 Jul 1;95:103208.

[5] Cree BAC, Arnold DL, Chataway J, Chitnis T, Fox RJ, Pozo Ramajo A, et al. Secondary Progressive Multiple Sclerosis: New Insights. Neurology [Internet]. 2021 Aug 24 [cited 2022 Jan 18];97(8):378–88. Available from: https://pubmed.ncbi.nlm.nih.gov/34088878/.

[6] Cree BAC, Arnold DL, Chataway J, Chitnis T, Fox RJ, Pozo Ramajo A, et al. Secondary Progressive Multiple Sclerosis: New Insights. Neurology [Internet]. 2021 Aug 24 [cited 2022 Jan 18];97(8):378–88. Available from: https://pubmed.ncbi.nlm.nih.gov/34088878/.

[7] Sand IK, Krieger S, Farrell C, Miller AE. Diagnostic uncertainty during the transition to secondary progressive multiple sclerosis. Mult Scler [Internet]. 2014 Oct 11 [cited 2022 Jan 18];20(12):1654–7. Available from: https://pubmed.ncbi.nlm.nih.gov/24493475/.

[8] D'hooghe MB, Haentjens P, Van Remoortel A, De Keyser J, Nagels G. Self-reported levels of education and disability progression in multiple sclerosis. Acta Neurol Scand. 2016 Dec 1;134(6):414–9.

[9] Lavorgna L, Brigo F, Moccia M, Leocani L, Lanzillo R, Clerico M, et al. e-Health and multiple sclerosis: An update. Multiple Sclerosis Journal. 2018 Nov 1;24(13):1657–64.

[10] Manrique de Lara A, Peláez-Ballestas I. Big data and data processing in rheumatology: bioethical perspectives. Clin Rheumatol [Internet]. 2020 Apr 1 [cited 2022 Mar 25];39(4):1007–14. Available from: https://pubmed.ncbi.nlm.nih.gov/32062767/.

[11] Altmann P, Hinterberger W, Leutmezer F, Ponleitner M, Monschein T, Zrzavy T, et al. The smartphone app hamster for tracking patient-reported outcomes in people with multiple sclerosis: Protocol for a pilot study. JMIR Res Protoc. 2021 May 1;10(5).

[12] Briggs FBS, Thompson NR, Conway DS. Prognostic factors of disability in relapsing remitting multiple sclerosis. Mult Scler Relat Disord. 2019 May 1;30:9–16.

[13] Tepavcevic DK, Pekmezovic T, Stojsavljevic N, Kostic J, Basuroski ID, Mesaros S, et al. Change in quality of life and predictors of change among patients with multiple sclerosis: A prospective cohort study. Quality of Life Research. 2014;23(3):1027–37.