Study Protocol w/ Statistical Analysis Plan

Last Updated 10/17/2022

IRB

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1) Protocol Title

Optimizing After Visit Instructions in an Outpatient Academic Rheumatology Clinic: A Prospective Randomized Open Label Trial

2) Objectives

The aim of this study is to assess the quality of standardized after visit instructions (AVI) and patient teach back in an outpatient academic rheumatology clinic by measuring patient retention of disease management and overall patient satisfaction. We propose a prospective randomized open label trial to determine if the presence of optimized and standardized discharge processes lead to better comprehension and retention of a patient's management plan.

Primary outcome will be level of retention based on the Follow-up Telephone Protocol.

Secondary outcomes assessed will include level of patient satisfaction based on our Post visit Survey and after visit instructions meeting patients' health literacy levels measured from the REALM-A.

3) Background

Patient education is an essential aspect of administering high quality care. How well patients understand their diagnoses and implement their plan of care is based on a multitude of factors that can drastically impact disease outcomes.[1,2] One of the key social determinants that affects a patients ability to comprehend and act on their medical conditions is health literacy (HL). The Center for Disease Control (CDC) defines two different types of HL in their updated Healthy People 2030 initiative. Personal HL is "the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others". Organizational HL is "the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and action for themselves and others". These new definitions of HL now acknowledge that organizations have a responsibility, from a public health perspective, to address HL and optimize their approach to varying levels of personal HL.[3]

In 2003 the National Assessment of Adult Literacy (NAAL) preformed a large-scale survey of both literacy and HL. It showed that 36% of adults had basic or below basic HL skills. Of the patients that had the lowest health literacy they tended to be older than 65 years old, hispanic or black, male, less than a high school education, and at or below the poverty line.[4] Low HL has been linked to poor health outcomes including in rheumatic diseases such as rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).[5,6] Various studies have been performed assessing literacy rates in rheumatology clinics utilizing the tool, the Rapid Estimate of Adult Literacy in Medicine (REALM). These studies have shown that a range of 10.3% to 19% of patients, within rheumatology clinics, have less than a 9th grade reading level.[7-9] Various strategies have been implemented to address the need for improving patients understanding of their medical conditions and management. The American Medical Association and the National Institute of Health have recommended that medical information be written at a 6th grade level. [10] However a recent study looking at the medical information sheets for common rheumatologic drugs from prominent rheumatology organizations in Canada, the UK, and Australia, consistently showed readability scores higher than the 9th

grade level.[11] The “teach-back” (TB) method, where patients repeat in their own words, instructions from the provider is a strategy used to bridge gaps in health literacy. In the emergency room setting TB has been shown to lead to less revisits and better retention of instructions.[12] Teach back communication in rheumatology clinics has been shown to improve overall medication compliance.[13] In the emergency room setting studies have shown that simplified and standardized after visit instructions can help increase patients overall understanding of their ER visit.[14]

An initial retrospective study showed us that written AVI were an underutilized resource in the Rush University Medical Center Rheumatology Clinic (RUMCRC). This retrospective assessment also showed that patients with more medications, higher comorbidity, and learning preferences that favor written AVI, did not receive more AVI.

For this study we seek to implement various strategies in an academic outpatient rheumatology setting that will address gaps in health literacy. These will include simple, standardized discharge instruction and patient teach back. With these strategies implemented, we will assess patients’ retention of knowledge and comprehension of medical instructions. We will also determine the feasibility of implementing these strategies in a rheumatology clinic in terms of time. Long-term studies will analyze how these interventions may have impacted various health related outcomes and patient reported outcomes.

4) Inclusion/Exclusion Criteria

Inclusion Criteria

- Age > 18 yo
- Patients seen in the RUMCRC

Exclusion Criteria

- Tele-medicine visits
- English is not the primary language. This is due to inability of all providers to provide custom AVI due to language limitations

5) Procedures Involved

There will be three cohorts in total: the control group, the standardized AVI only group, and the standardized AVI with teach back group. The control group will involve patients receiving the current standard discharge process at the RUMCRC. The standardized AVI only group will involve patients receiving written standardized AVI that the patients will take home. The standardized AVI with teach back group will include standardized written AVI with the patient repeating to the provider which changes, and future management had been agreed upon during the visit. The standardized AVI will include a text template that providers will use to write customized after visit instructions for the patient that will be in addition to the after-visit summary.

Providers will be taught the standardized discharge approach through in-person education modules and handouts. This education will encompass a 30 minute didactic going over the tenants of the standardized AVI, accessing standardized AVI templates on EMR, and how

to preform appropriate teach back with patients. No providers that are implementing the intervention will be a part of the research team.

Patients will be randomized before the office visit. Patients will not be told which group they are in unless they explicitly ask. Providers will be told which intervention group a patient is a part of. If a patient is in the control group the providers will not be informed as to not impact behavior. Because of the randomization we believe confounding variables will be distributed equally throughout the groups.

All patients included in the prospective study will complete an arthritis adapted REALM (REALM-A) form at the observed visit to evaluate their health literacy level. All patients included in the prospective study will also complete an immediate post appointment questionnaire (Post Visit Satisfaction Survey) that will allow them to provide feedback, rate visit satisfaction, and evaluate how after visit instructions were implemented during the visit.

Within 1-2 weeks after the patient's initial visit, a standardized phone call will be performed where patients will be asked specific questions pertaining to their visit in terms of diagnosis, medications, plan, and follow-up appointments. We will score whether their understanding of their disease and management corresponds with what was discussed at the prior visit. This will be performed for all groups. This score will be assessed as our primary outcome.

Baseline data points will be collected for patients in both cohorts including: Basic demographics, new patients versus follow-up visit, MD-HAQ scores, REALM-A score, rheumatologic diagnosis, medications, Charleson co-morbidity scores, barriers to learning, and patient preferences for learning.

After the study, AVI provided will be assessed using Flesch-Kincaid Readability Scores and Grade levels to see how they correspond to patients baseline literacy.

6) Data Management

Summary tables (descriptive statistics and/or frequency tables) will be provided for all variables. Continuous variables will be summarized with descriptive statistics (n, mean, standard deviation, range, and median). Ninety-five (95) percent confidence intervals may also be presented, as appropriate.

Frequency counts and average will be provided for categorical data.

Data will be coded when stored for analysis. Data that is obtained for this study will be coded when stored for analysis. This data will be held under password locked computers that can only be accessed by persons who have approval for access via the IRB. Those that have access to the coded data will require a key to interpret the data. All data will be deleted at the completion of the study.

7) Risks/Benefits

Given the nature of intervention there is little to no risk in terms of patient outcomes. This study will collect private, identifiable information about human subjects. The main risk is to

subjects' confidentiality should an individual outside of the study team access the study data.

Benefits of this study, particularly in the intervention cohort, would be the potential for improved patient comprehension and retention of various aspects of their health.

8) Resources Available

REDCAP will be utilized to store and analyze data. SPSS will be utilized to perform statistical analysis.

Joshlean Faire a clinical research coordinator at the RUMC Division of Rheumatology will assist with the consent process and recruitment process.

9) Confidentiality

Data will be stored under password protection with coded data on laptops owned by Dijo Joseph

Data will only be accessible by those that are directly involved with obtaining data

10) Consent Process

Patients will be contacted with permission from their primary providers prior to their scheduled visit to discuss their voluntary participation in the study. If they agree to participate informed consent will be completed over the telephone and documents will be reviewed and signed electronically. If this is not feasible, they will be instructed to arrive 30 minutes early to their appointment to perform an in person consent. During this period they will sign a corresponding consent form outlining the risks/benefits and procedures of this study.

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