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General Study Information

Principal Investigator: Victor Montori, M.D.

Study Title: Decision Aids for patients with Nonvalvular Chronic Atrial Fibrillation (DA4AFib)

Protocol version number and date: Protocol Version 2, 01/24/2019

Research Question and Aims

Aims, purpose, or objectives: We aim to develop, in close collaboration with stakeholders, evidence-based decision aids for patients with nonvalvular chronic Atrial Fibrillation

Background:

A big public health problem: strokes in patients with atrial fibrillation - Atrial fibrillation (AF) is associated with ~5-fold increase in the risk of stroke[1-3]. Stroke affects 25-35% of patients with AF in their lifetime[4-6] and is usually more severe and twice as likely to be fatal (19-35%) than non-AF strokes (5-14%)[7]. Stroke survivors live with physical disabilities and burden their families and caregivers socially, physically, emotionally, and financially[8-15]. Joo et al. estimated that caregivers spend 8.5 hours/week and > $8,000/year in the care of their patients with AF-related strokes[15].

A failure of evidence translation – Large randomized trials have demonstrated the unequivocal and substantial benefits of anticoagulation in reducing the risk of AF-related strokes[1,16-18], yet many at-risk patients do not receive these benefits. In their systematic review of 29 studies from 1997-2008, Ogilvie et al. found fewer than 50% of high-risk AF patients were treated with anticoagulation[19] while more recent registry assessments document an anticoagulation gap of 20-50%, with a smaller but substantial gap (20-30%) in specialty practice and very high-risk patients[20,21]. This practice gap is multifactorial: Clinicians fail to prescribe anticoagulation in high-risk patients, due to failure to recognize high risk patients[22], misperceptions about the efficacy and safety of aspirin (no longer recommended for stroke prevention in AF)[23], and fear of causing disabling bleeding[24-27]. Despite new evidence of safety and efficacy in risky groups, such as the very old, this pattern continues[19,24,25]. Of patients prescribed anticoagulation, 30-50% discontinue the drug within 12 months[24,25,28-31]. Nonadherence is also multifactorial[32-35]: In some cases, patients perceive no benefit or overestimate their risk of bleeding[26]. Inadequate understanding of the value of anticoagulation with warfarin may reduce patient motivation to overcome the inconvenience of periodic INR monitoring and dietary alterations[26,36-38]. In order to translate anticoagulation guidelines into practice and reap the benefits of anticoagulation therapy, patients' and clinicians' challenges in initiating and implementing anticoagulation must be addressed.

Experts recommend shared decision making (SDM) to realize the benefits of anticoagulation – In response to these challenges, the 2014 guidelines from the American Heart Association, American College of Cardiology, and The Heart Rhythm Society for the management of patients with AF formulated a strong class I

recommendation for patients and clinicians to make decisions together to individualize antithrombotic care[1]. Their call for SDM opens an opportunity and a challenge—viz., to improve the quality of care by making anticoagulation decisions more consistent with each patient's individualized stroke risk and with their situation, including comorbid conditions and socio-personal context.

To assist patients and clinicians to reach SDM about treatment options for patients with nonvalvular chronic Atrial Fibrillation screening we aim to develop evidence-based decision aids to complement the clinical encounters. Our goal is to promote evidence-based patient-centered care. Ideally, this care should reflect the research evidence about anticoagulation treatment. It should also reflect the values and preferences of the informed patient.

Our research team has approximately 15 years of experience designing and evaluating decision aids. These aids were designed with patient and clinician input and developed iteratively at the point-of-care. Randomized trials have found these aids acceptable, useful, desirable by both patients and clinicians; and effective in improving patient knowledge and participation in choice, and the quality of treatment decisions.

Content and Evidence: These will be evidence-based decision aids. Thus, they will present the best available comparative effectiveness evidence about the advantages and disadvantages related to different treatment choices and present, where pertinent and possible, estimates of the probability of these outcomes.

Study Design and Methods

Methods:

Observations of Clinical Encounters:
To complete data collection, encounters of patients scheduled for AF treatment will be observed (by a study team member and/or using a video recording device) at Mayo Clinic Rochester and may be observed at Mayo Clinic Health System sites in Minnesota. We will identify patterns of patient-clinician conversations regarding AF treatment. This information will be summarized by our research team and integrated with prior knowledge from previous decision support work.

For Mayo Clinic Health System sites, we will seek approval from the sites to allow a member of the study team (from Mayo Clinic Rochester) to have access to clinicians and patients and conducts observations. Approval will be obtained prior to any observations conducted at the Mayo Clinic Health System sites.

We will explicitly indicate during an appointment if we plan to use a recording device in the room. These recordings will be used to further review and debrief with the team members on the protocol that cannot all be present at one time for the encounter.

Interviews and Focus Groups:

In order to better understand the emotional experiences and problems of home-care management that patients with AF go through, we would like to conduct interviews and focus groups with patients and caregivers. Settings for recruitment may include: screening and approach of patients coming in for cardiology appointments at Mayo Clinic; members of online support groups; snowballing and referral; as well as the Stakeholder Group and other patients of the University of Utah, our partner site. To complete data collection, interviews and/or focus groups of patients and their caregivers (if applicable) will be conducted study team member and may be video or audio recorded.

Field Testing and Iterative Development:
We will create initial prototypes informed by the observations described above and in consultation with experts and stakeholders in the field. We will consult The International Patient Decision Aids Standards (IPDAS) for guidance during the construction of decision aids. These prototypes will be presented to patients for input and refinement, including the KER Unit's Patient Advisory Group.

After making as many revisions as necessary, a study team member may introduce patients to the decision aid(s) and observe or record encounters of these patients with their clinicians. We will then further develop the prototype decision aids based on their performance. For field testing and iterative development, encounters of patients scheduled for AF treatment will be observed (by a study team member and/or using a video recording device) at Mayo Clinic Rochester and Mayo Clinic Health System sites in Minnesota. Patients may be introduced to the aid, with informed consent, prior to the encounter. In these cases, we may ask the patients to consider pre-encounter materials and provide their insight prior to the visit. Study team members involved with the recruitment process may also follow up with patients and clinicians following their visit to get feedback regarding the decision aids.

We will explicitly indicate during an appointment, focus group and/or interview if we plan to use a recording device in the room. These recordings will be used to further review and debrief with the team members on the protocol that cannot all be present at one time for the encounter. Patients may alternately choose to have an in-person observer in the room in lieu of a recording device. Based on communication patterns identified, refinements to the tool will be made.

Iterations of the prototypes will be developed with input from all study team members and experience to-date. The process of field testing will continue until the study team, stakeholders, and PAG members reach a consensus that the prototypes are successful in involving patients in the decision-making process and satisfies IPDAS criteria. Based on our experience, up to 20 versions may be necessary to achieve this goal.

All patients who participate in the study will asked for their permission to use the data collected through their participation in the study (such as video recordings) for ongoing registry purposes for IRB-approved research, training and educational purposes. In situations such as video recordings, files will only be retained for future use as long as both the clinician and the patient in the video agree to this.

Resources: *Describe the available resources to conduct the research (personnel, time, facilities, mentor commitment, etc.)*:
Dr. Montori is available to provide oversight as the Principal Investigator; Juan Pablo Brito is Co-Principal Investigator; Ian Hargraves is a Co-Investigator and service designer leading decision aid design and

development; Kevin Shaw is a service designer carrying out decision aid design and development; Angela Sivly and Emma Behnken will help with study coordination.

☐ (1a) This is a multisite study involving Mayo Clinic and non Mayo Clinic sites. *When checked, describe in detail the research procedures or activities that will be conducted by Mayo Clinic study staff.*

☐ (1b) Mayo Clinic study staff will be engaged in research activity at a non Mayo Clinic site. *When checked, provide a detailed description of the activity that will be conducted by Mayo Clinic study staff.*

Subject Information

Target accrual is the proposed total number of subjects to be included in this study at Mayo Clinic. A "Subject" may include medical records, images, or specimens generated at Mayo Clinic and/or received from external sources.

Target accrual: 200

Subject population (children, adults, groups): Adults, Patients, Clinicians and PAG members

Activity	Participant	Inclusion Criteria	Exclusion Criteria	Consent / Authorization
Observations of Clinical Encounters And Field Testing and Iterative Development	Patients	- Adults ≥ 18 years - Appointment for AF treatment	- Major barriers to providing informed consent (i.e. dementia, severe hearing or visual impairment)	Written consent
	Clinicians	- Clinicians who meet with patients for AF treatment	None	Written consent
	PAG Members	- Adults ≥ 18 years - Member of the KER Unit PAG	None	Oral consent / HIPAA does not apply

Research Activity

Check all that apply and complete the appropriate sections as instructed.

1. ☐ **Drug & Device**: Drugs for which an investigational new drug application is not required. Device for which (i) an investigational device exemption application is not required; or the medical device is

cleared/approved for marketing and being used in accordance with its cleared/approved labeling. (Specify in the Methods section)

2. ☐ **Blood**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. ☐ **Biological specimens other than blood**: Prospective collection of human biological specimens by noninvasive means that may include: urine, sweat, saliva, buccal scraping, oral/anal/vaginal swab, sputum, hair and nail clippings, etc.

4. ☐ **Tests & Procedures:** Collection of data through noninvasive tests and procedures routinely employed in clinical practice that may include: MRI, surface EEG, echo, ultrasound, moderate exercise, muscular strength & flexibility testing, biometrics, cognition testing, eye exam, etc. (Specify in the Methods section)

5. ☒**Data** (medical record, images, or specimens): Research involving use of existing and/or prospectively collected data.

6. ☒ **Digital Record**: Collection of electronic data from voice, video, digital, or image recording. (Specify in the Methods section)

7. ☒ **Survey, Interview, Focus Group:** Research on individual or group characteristics or behavior, survey, interview, oral history, focus group, program evaluation, etc. (Specify in the Methods section)

☐ NIH has issued a *Certificate of Confidentiality* (COC). *When checked, provide the institution and investigator named on the COC and explain why one was requested*. _____

Biospecimens – Categories 2 and 3

(2) Collection of blood samples. When multiple groups are involved copy and paste the appropriate section below for example repeat section b when drawing blood from children and adults with cancer.

a. **From healthy, non-pregnant, adult subjects who weigh at least 110 pounds**. For a minimal risk application, the amount of blood drawn from these subjects may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

b. **From other adults and children considering age, weight, and health of subject.** For a minimal risk application, the amount of blood drawn from these subjects may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period, and collection may not occur more frequently than 2 times per week.
   Volume per blood draw: _____ml
   Frequency of blood draw (e.g. single draw, time(s) per week, per year, etc.) _____

(3) Prospective collection of biological specimens other than blood: _____

Review of medical records, images, specimens – Category 5

For review of existing data: provide a date range or an end date for when the data was generated. The end date can be the date this application was submitted to the IRB. Example: *01/01/1999 to 12/31/2015* or all records through *mm/dd/yyyy*.

Date Range:

Check all that apply (data includes medical records, images, specimens).

☐ (5a) Only data that exists before the IRB submission date will be collected.

☐ (5b) The study involves data that exist at the time of IRB submission **and** data that will be generated after IRB submission. Include this activity in the Methods section.
Examples

- The study plans to conduct a retrospective chart review and ask subjects to complete a questionnaire.
- The study plans to include subjects previously diagnosed with a specific disease and add newly diagnosed subjects in the future.

☐ (5c) The study will use data that have been collected under another IRB protocol. Include in the Methods section and enter the IRB number from which the research material will be obtained. *When appropriate, note when subjects have provided consent for future use of their data and/or specimens as described in this protocol*.

Enter one IRB number per line, add more lines as needed

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ Data ☐ Specimens ☐ Data & Specimens _____

☐ (5d) This study will obtain data generated from other sources. Examples may include receiving data from participating sites or an external collaborator, accessing an external database or registry, etc. Explain the source and how the data will be used in the Methods section.

☒ (6) Video audio recording: *Describe the plan to maintain subject privacy and data confidentiality, transcription, store or destroy, etc.*


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HIPAA Identifiers and Protected Health Information (PHI)

Protected health information is medical data that can be linked to the subject directly or through a combination of indirect identifiers.

Recording identifiers (including a code) during the conduct of the study allows you to return to the medical record or data source to delete duplicate subjects, check a missing or questionable entry, add new data points, etc. De-identified data is medical information that has been stripped of all HIPAA identifiers so that it cannot be linked back to the subject. De-identified data is **rarely** used in the conduct of a research study involving a chart review.

Review the list of subject identifiers below and, if applicable, check the box next to each HIPAA identifier being recorded at the time of data collection or abstraction. Identifiers apply to any subject enrolled in the study including Mayo Clinic staff, patients and their relatives and household members.

Internal refers to the subject's identifier that will be recorded at Mayo Clinic by the study staff.
External refers to the subject's identifier that will be shared outside of Mayo Clinic.

Check all that apply:	INTERNAL	EXTERNAL
Name	x	
Mayo Clinic medical record or patient registration number, lab accession, specimen or radiologic image number	x	
Subject ID, subject code or any other person-specific unique identifying number, characteristic or code that can link the subject to their medical data	x	
Dates: All elements of dates [month, day, and year] directly related to an individual, their birth date, date of death, date of diagnosis, etc. **Note:** Recording a year only is not a unique identifier.	x	
Social Security number		
Medical device identifiers and serial numbers		
Biometric identifiers, including finger and voice prints, full face photographic images and any comparable images	x	
Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers, email address	x	
Street address, city, county, precinct, zip code, and their equivalent geocodes	x	
Phone or fax numbers	x	
Account, member, certificate or professional license numbers, health beneficiary numbers		
Vehicle identifiers and serial numbers, including license plate numbers		
Check 'None' when none of the identifiers listed above will be recorded, maintained, or shared during the conduct of this study. (exempt category 4)	☐ None	☐ None

Data Analysis

☒ No statistical information. *If checked, please explain*: This study is for the development (not testing) of a decision aid.

Power analyses may not be appropriate if this is a feasibility or pilot study, but end-point analysis plans are always appropriate even if only exploratory. Provide all information requested below, or provide justification if not including all of the information.

Power Statement:

Data Analysis Plan:

Endpoints
Primary:
Secondary: