Family history in primary care

The systematic collection of family health history (FHH) can identify individuals at increased risk for common diseases including cardiovascular disease, diabetes, and cancer; many evidence-based guidelines rely upon risk stratification using FHH to guide the appropriate use of alternative (non-routine) screening procedures (such as breast MRI), diagnostic tests, and/or genetic counseling. Unfortunately there are several barriers to the adequate collection of FHH within routine primary care: lack of patient preparation to provide FHH[1,2], the amount of time needed to collect FHH [3,4], lack of standardization, and limited training in synthesizing FHH data into a clinically actionable care plan[1,5-7]

MeTree

To address these issues, we have created a web-based patient-entered risk stratification and clinical decision support tool, MeTree, with the following design goals:

- Develop a collection interface that is easy for patients to use and facilitates collection of all the necessary FHH and personal history components to perform risk stratification (full 3-generation pedigree with age of disease onset, current age or age of death, and cause of death for each relative)

- Provide lay level and technical decision support that is clinically actionable for providers, activating for patients, and easy for patients and providers to understand

- Base decision support upon guidelines widely accepted by PCPs and provide just-in-time education within the reports about what criteria triggered the recommendation, points to consider about the recommendation, data such as NNT, references to the guidelines, and links to additional resources

- Capitalize on the patient-provider encounter to encourage discussions of preventive health and disease risk management.

MeTree will be available as an independent web-service that provides risk stratification and clinical decision support for the following conditions: <u>breast cancer, ovarian cancer, colon cancer, hereditary cancer syndromes, coronary artery disease, hereditary cardiovascular conditions, stroke, aortic aneurysm, diabetes, and hereditary liver diseases (such as hemochromatosis)</u>. An example of the patient and provider reports and a demo of the tool is available at fh.oneview.me.

Benefits to providers and patients

- *Reduces burden on providers*
    - Decreased data collection: Patients enter all of their information independently at home prior to their appointment.
    - Calculates scores for you (e.g. Gail score, Framingham risk score, etc.)
    - Provides simple straightforward action-oriented recommendation tailored to the patient
    - Does not impact workflow or hijack discussions with patients based on experience of past providers who have used MeTree in their clinics[8].

- *Improves quality of data collection*
    - Educates patients about what to collect and how to collect FHH from family members
    - Patients may login and out to collect more information as often as needed
    - FHH collected with MeTree is of higher quality than what is possible to collect within the constraints of current practice (paper in review – available upon request).

- *Improves quality of care*

- o Over 30% of patients of primary care patients are found to be at increased risk for at least one disease after using MeTree (90% were not previously identified as at risk)
  - o Provides just-in-time education within the reports.
  - o Provides number needed to treat/screen when appropriate.
  - o Links to gene tests and pharmacogenomic testing when appropriate.
  - o Indicates when new technologies (ex: calcium scoring CT) have clinical utility
- *Promotes patient participation in care*
  - o Engages patients in their care and encourages active participation
  - o Potential to develop into shared-decision making tool
- *Will link to EMR during years 2-3*

Study Design

To study the impact of MeTree in a diverse group of real world primary care settings we are providing access to MeTree in five health care systems across the country (Duke, Essentia Health, Medical College of Wisconsin, Travis Air Force base, and University of North Texas). This study is a cluster-randomized controlled Hybrid type II Implementation-Effectiveness study. At each site there will be at least one control clinic to evaluate concurrent trends in screening and referral practices. Among the intervention clinics there will be a pre-implementation, implementation, and post-implementation phase to the study.

In the <u>pre-implementation</u> phase data will be gathered from clinical staff and administrators to identify the best method for integration of MeTree and education regarding how MeTree works and what to expect. Using the information gathered, an implementation plan will be developed with feedback from the site PIs and local physician champions. One key area will be how providers receive their reports until EMR linkage is achieved *(at Duke reports will import as PDFs at study start)*.

In the <u>implementation</u> phase the system will be integrated into the clinical sites and tested with feedback from local staff regarding problems and potential solutions. During this phase patient recruitment will begin.

In the <u>post-implementation</u> phase the system will be fully optimized for each clinic and recruitment will continue until completed.

Study Flow

<u>Patients</u>: All adult patients with upcoming primary care appointments will be invited to participate (via letter or call). Interested patients contact a Duke central study coordinator who creates an account in English or Spanish and emails a link to access the site. On the site they complete information about themselves and how they are accessing the site and sign an electronic informed consent document. After that they are sent a link to the baseline survey (see measures) and then are able to access MeTree with its embedded education. Those who consent to be enrolled will be provided a web link that contains education on how to collect FHH and a link to MeTree that will remain active until after their appointment date. For those who do not have access to the internet, a laptop or tablet will be available by appointment with the local site study coordinator. Patient reports and pedigrees are generated upon completion of MeTree and can be saved or printed immediately. Providers receive their report through method identified in the implementation plan. Patients complete a survey at 3 and 12 months (baseline survey with a few additional questions).

<u>Providers</u>: Providers will sign paper consents administered by the site PI. All will be invited to electronically complete the organizational readiness to change survey during pre-implementation and a brief 14-item check box style "user experience" survey 3 months post-implementation.

<u>Measures/Outcomes</u>: The primary outcomes are uptake/use of the tool by patients and providers, uptake of risk-stratified prevention guidelines, and patient lifestyle. Data on screening studies, labs, office visits, referrals, and new diagnoses will be captured via electronic data pulls. Patient-centered measures are captured on the surveys, which consists of:

- Medication adherence (morisky)
- Readiness to change for diet, exercise, smoking, cancer screening
- Activation (patient activation measure)
- Quality of life (SF-12 and visual analog measure)
- Diet (rapid food screener)
- Exercise (Stanford brief activity survey)
- Tobacco and alcohol use
- Cancer screening (HINTS)
- Satisfaction

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