

## Providing Patient Education: Impact on Quantity and Quality of Family Health History Collection

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### **Abstract:**

*Background:* Family health history (FHH) is an underutilized tool in primary care to identify and risk-stratify individuals with increased cancer risk. *Objective:* Evaluate the influence of patient education on quantity and quality of FHH entered into a primary care-based software program, and impact on the program's cancer risk management recommendations. *Design:* Two primary care practices within a larger type II hybrid implementation-effectiveness controlled clinical trial. *Participants:* English speaking non-adopted patients with a well visit appointment December 2012–March 2013. *Interventions:* One to two weeks prior to their well visit appointment, participants entered their FHH into the program. Participants were then provided educational materials describing key FHH components. They were instructed to use the interval to collect additional FHH information. Patients then returned for their scheduled appointment, and updated their FHH with any new information. *Main Measures:* Percentage per pedigree of relatives meeting individual quality criteria. Changes made after patient education and changes to recommendations for surveillance, chemoprevention or genetic counseling referral. *Key Results:* Post patient education, pedigrees exhibited a greater percentage (per pedigree) of: deceased relatives with age at death (84 vs. 81 %  $p = 0.02$ ), deceased relatives with cause of death (91 vs. 87 %  $p = 0.02$ ), relatives with a named health condition (45 vs. 42 %  $p = 0.002$ ), and a greater percentage of relatives with high quality records (91 vs. 89 %  $p = 0.02$ ). Of 43 participants with pedigree changes that could trigger changes in risk stratified prevention recommendations, 12 participants (28 %) received such changes. *Conclusions:* Patient education improves FHH collection and subsequent risk stratification utilized in providing actionable evidence-based care recommendations for cancer risk management.

**Keywords:** Family history | Patient education | Risk assessment | Clinical decision support

## Article:

### Introduction

Family health history (FHH) is an important component of patient care, facilitating risk stratification and application of evidence-based care for common diseases such as cancer, heart disease and diabetes [1–5]. FHH remains one of the strongest predictors of disease risk [6], has implications for other family members and is increasingly utilized in risk stratification for cancer surveillance (e.g. breast MRI), diagnostic testing, and/or genetic counseling referral [7–11]. Elements of FHH required in sufficient detail to yield meaningful risk stratification include: (1) three generations of relatives, (2) relatives' lineage (e.g. maternal or paternal), (3) relatives' gender, (4) up-to-date information, (5) pertinent negatives noted, (6) age of disease onset for affected relatives, and for deceased relatives (7) age of death, and (8) cause of death [12–15]. However, multiple barriers impede collection and accessibility of adequate FHH. These include: absence of reimbursement for time required to collect FHH [16]; lack of time secondary to competing clinical demands [17–21]; lack of training in gathering and interpreting FHH information [17]; and limitations in the patient's knowledge of their own FHH [22]. While adoption of electronic medical records (EMRs) is anticipated to standardize and systematize collection, interpretation and presentation of patient data, EMRs do not effectively address these barriers, and may actually add to them [23]; Collectively, these barriers result in absent FHH or insufficient FHH to assess disease risk [24, 25].

To address this problem, Duke University, The University of North Carolina at Greensboro and Cone Health System collaborated to create the Genomedical Connection, and developed the genomic medicine model for primary care [26]. The model, described in detail elsewhere, integrates principles of the Health Belief Model and Adult Learning Theory to link education, FHH collection, patient activation, and clinical decision support in creating recommendations for FHH risk-stratified prevention strategies nested within primary care practice daily workflow. The model's core delivery mechanism is a self-administered patient-facing software program, called MeTree. Briefly, MeTree gathers patient FHH on 48 diseases and provides real time risk stratification and clinical decision support for five pilot diseases: breast cancer, ovarian cancer, colon cancer, thrombophilia, and hereditary cancer syndromes. Upon completion, patients are given a copy of their pedigree and a "patient report" detailing salient aspects of their FHH for further discussion with their provider. Clinicians receive a copy of the pedigree, a tabular format of the FHH and a "provider report" detailing: actionable prevention and diagnostic strategies related to clinical decision support conditions; FHH elements triggering recommendations; and a summary of the risk stratification guidelines. Development and validation of MeTree is further described elsewhere [27]. A crucial component of MeTree's effectiveness is adequate patient education. Evidence concerning patient education in collecting FHH is minimal, but existing evidence primarily examines education preceding genetic counseling referrals [28–31]. This paper describes the effect of patient education regarding FHH collection and risk stratification on: quantity and quality of FHH data collected and changes in resulting care recommendations.

## Methods

### Study design, participants and intervention

This study was part of a larger type II hybrid implementation-effectiveness controlled clinical trial assessing the utilization and impact of MeTree in two community-based primary care practices in Greensboro, NC (referred to as the parent study for the purposes of this paper) [32]. In brief, all English speaking, non-adopted adult patients scheduled for a future well visit were contacted and invited to participate approximately 3 weeks before their scheduled visit. Patients who agreed to participate were consented and provided educational materials emphasizing why, what, and how to collect FHH by the study coordinator. Materials included a brochure (Online Resource 1) on why FHH and risk assessment is important for their own care, a booklet (Online Resource 2) on how to talk to their relatives and what information to collect (particularly the need to ask about age at onset, death status, and cause of death), and a worksheet (Online Resource 3) containing a list of diseases to ask about with a table to assist in documenting relatives' conditions. On the day of appointment, patients self-entered their FHH into MeTree which then generated previously described patient and provider reports.

In this sub-study, we evaluated the impact of patient education by inviting patients who met study criteria between December 2012 and March 2013 to complete MeTree prior to receiving the educational materials and provided an opportunity to revise their existing FHH afterwards. Patients who agreed to participate were consented and asked to self-enter their FHH into MeTree at a clinic kiosk prior to receiving any patient education (the pre-test). Upon completion of MeTree, participants were provided the educational materials, given 1–2 weeks to collect additional information (if desired), and return to update their existing FHH in MeTree with their newly acquired information at their scheduled well visit appointment (the post-test). Information in MeTree following the post-test was used to generate the clinical decision support for patient and provider reports. The study was approved by the IRB at each institution and the funder, US Army and Material Command.

### Data storage and outcomes measurement

FHH pedigree data entered into MeTree for both pre-test and post-test was stored in a SQL database and analyzed using R statistical software [33]. Descriptive demographic information was recorded on each participant completing pre-test for comparison to participants in the parent study. Time to complete MeTree during the pre-test was also recorded for comparison with the parent study. Finally, all changes to the pedigree (e.g. additions, removals, death status) from initial pre-test to post-test and any changes to recommendations for additional screening, diagnostic tests or referrals to genetic counseling that would have been generated by the pre-test were recorded for subsequent analysis.

### Statistical analysis

Following data collection we assessed baseline demographics of the sub-study and compared them to the parent study. Next we evaluated sub-study pedigrees before and after patient education describing types of changes, the percentage of sub-study making these changes and total number of changes for each type of change. Elements of a pedigree that contribute to a high quality FHH in generating appropriate risk stratified recommendations include: (1) three generations of relatives, (2) relatives' lineage (e.g. maternal or paternal), (3) relatives' gender, (4) up-to-date information, (5) pertinent negatives noted, (6) age of disease onset for affected relatives, and for deceased relatives (7) age of death, and (8) cause of death. The basic structure of MeTree meets the first 5 criteria automatically. High quality relatives were defined as relatives meeting one or more of the three non-automatic criteria described here. We assessed the remaining three individual elements required to define an adequate (high quality) FHH for risk stratification. For each pedigree this included the percentage of relatives with a condition who had an age at onset, the percentage of deceased relatives with an age at death, and the percentage of deceased relatives with a cause of death. We also assessed the percentage of relatives with a named health condition and total number of conditions reported in the pedigree. To examine change in completeness of FHH, we compared the average of these percentages (e.g. percent of deceased relatives with age at death) for all pedigrees before and after patient education. We then examined before and after pedigrees for changes in recommendations specific to breast cancer screening, colon cancer screening, and genetic counseling referral as an illustration of the impact of adequate FHH on risk stratified preventive screening actions.

To assess for potential test-maturation bias, we selected a measure (change in number of siblings) which theoretically should not vary between pre and post pedigrees and evaluated for differences. Similarly, we selected a measure (number of relatives with colon polyp information) that should only vary with education and not as a function of completing the pedigree twice. Statistical tests performed in analysis included Chi Square Test (for categorical variables), Paired *T* Test (for continuous variables) and ANOVA (for comparisons between study sample and parent study).

## **Results**

### Characteristics of study sample

One hundred consecutive participants were recruited and completed MeTree at enrollment. One did not return to update FHH and was therefore not included in analysis. Baseline demographics of the sub-study and parent study are detailed in Table 1. Participants in the sub-study were slightly more likely to be white and educated but were comparable to the parent study. The parent study population has been shown to be representative of the underlying clinic population [34]. Time to complete FHH prior to receiving education (sub-study) required an average of 6.6 more minutes than in the parent study when it was completed after education.

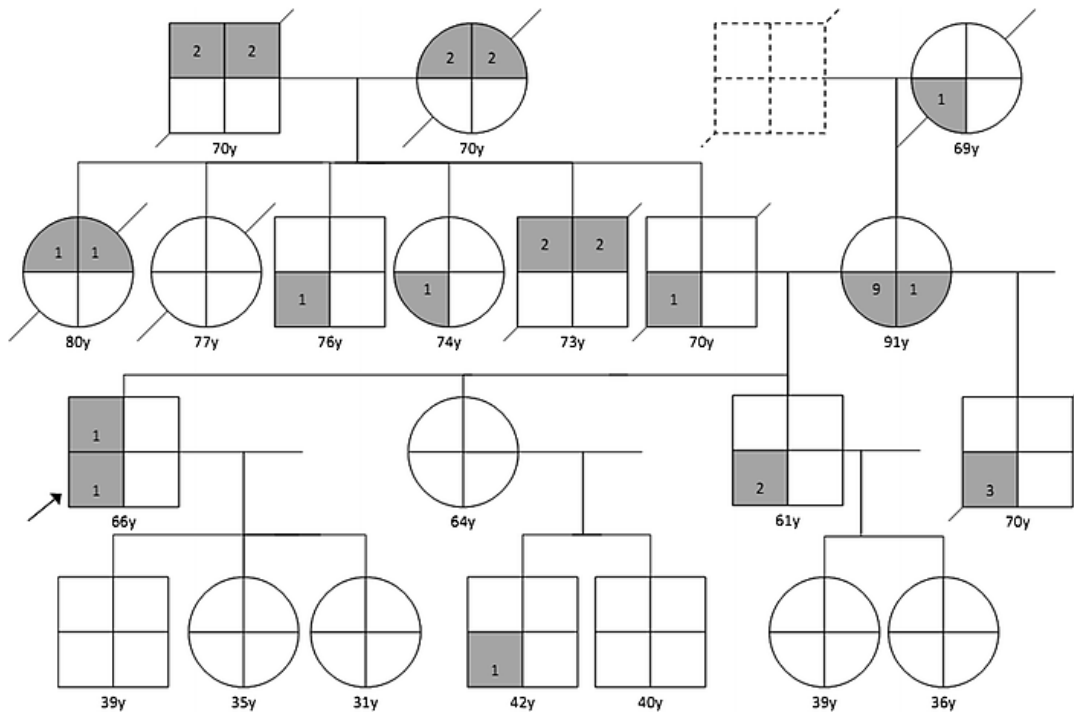
**Table 1** Baseline characteristics of sub-study and parent study

	<b>Sub-study (n = 100)</b>	<b>Parent study (n = 1,184)</b>	<b>P value*</b>
	<b>No. (%)</b>	<b>No. (%)</b>	
<b>Gender</b>			
Male	50 (50 %)	490 (41.4 %)	0.09
<b>Ethnicity</b>			
White	88 (88 %)	969 (81.8 %)	
Black	9 (9 %)	159 (13.5 %)	0.12
Other	2 (2 %)	56 (4.7 %)	
<b>Age</b>			
Mean (SD)	58.1 (11.4)	58.8 (11.8)	0.56
<50	21 (21 %)	250 (21.1 %)	
50–65	47 (47 %)	575 (48.6 %)	0.98
>65	31 (31 %)	359 (30.3 %)	
<b>Education</b>			
High school or less	10 (10 %)	158 (13.3 %)	0.35
Some college	17 (17 %)	245 (20.7 %)	
College degree	42 (42 %)	461 (38.9 %)	
Any graduate	30 (30 %)	320 (27.0 %)	
<b>Minutes to complete MeTree</b>			
Mean (SD)	33.6 (19.1)	27 (12.23)	<0.01

\* *P* value denotes two-sample test comparing proportion (or mean) for inequality between sub-study and parent-study

#### Illustrative pedigree pre and post

An illustrative example of a participant pedigree before education and revised after patient education demonstrating typical pedigree changes is shown in Fig. 1. Grey quadrants represent revisions in the post pedigree with numbers indicating the quantity of changes. The upper left quadrant represents a change in disease status with potential impact on care recommendations, while the upper right quadrant represents change in age of onset for a disease with potential impact on care recommendations. Changes in lower left and lower right quadrants represent changes in disease status and age of onset that do not impact care recommendations for the pilot conditions.



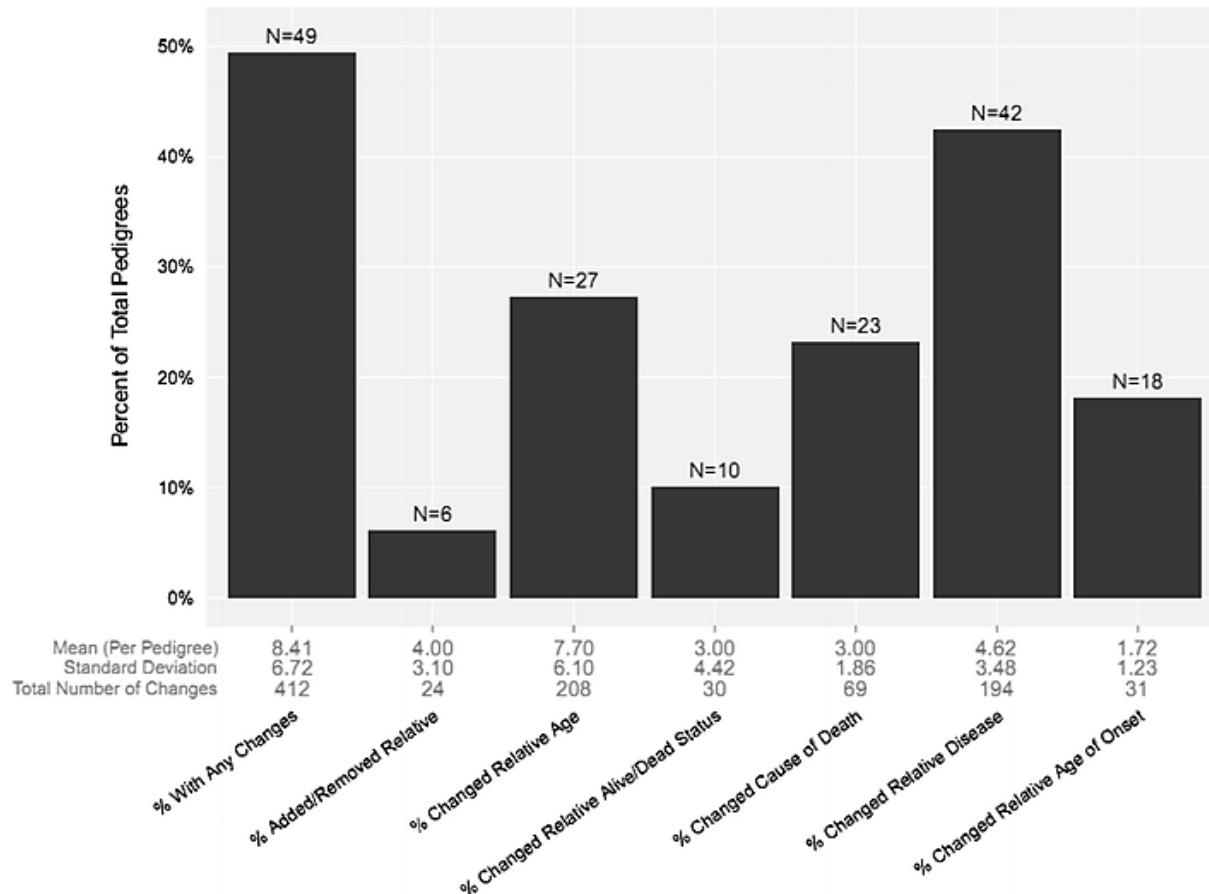
**Fig. 1** MeTree pedigree before and after education. This example pedigree illustrates changes to a pedigree after patient education. *Squares* are male relatives, *circles* are female relatives, a *diagonal line* corresponds to a deceased relative and a *dashed line* represents a relative for whom no data is available. *Shaded quadrants* represent a change in the post education pedigree with the number in the quadrant corresponding to the number of changes in that category. The *upper left quadrant* is a change in disease status; the *upper right quadrant* is a change in the age of onset of a disease. Both *upper quadrants* represent changes that influence a care recommendation. The *lower left quadrant* corresponds to a change in disease status not affecting recommendations, while the *lower right quadrant* represents a change in age of onset not affecting recommendations. The *diagonal black arrow* represents the proband

### Test-maturation bias

To investigate potential repeated testing bias (participants may perform better on second MeTree session due only to familiarity with MeTree) associated with two or more MeTree sessions, we examined the change in number of siblings reported before and after patient education for each pedigree. We hypothesized this number should not change as a function of education, and would only change as a function of application familiarity. We found no changes in number of siblings for any pedigree between pre and post MeTree sessions. Similarly, we sought to examine an attribute of the pedigree that should only change with patient education, to compare sub-study post session with the parent study. In the absence of any test-maturation bias, the attribute should be comparable between the sub-study and parent study, as both received patient education before a MeTree session. We found no difference in number of relatives with colon polyps entered into the pedigree between sub-study and parent study (mean 0.51 vs. 0.59 relatives  $p = 0.42$ ).

## Changes to FHH following receipt of patient education

Participants completing a revised pedigree after receiving patient education (post-test) made several types of changes to their initial (pre-test) pedigree. These changes are illustrated in Fig. 2 and include: adding or removing a relative; changing, adding, or removing the age of a relative (includes age of death if relative deceased); changing Alive/Deceased status of a relative; changing cause of death for a deceased relative; changing, adding, or removing diseases for a relative; and changing, adding or removing age of disease onset. Half of the participants made changes to their pedigree following education. The most common changes were for disease status (42 %), age (27 %) and age of disease onset (18 %). Among those that made any change to relatives in their pedigree, the average number of changes per pedigree was 8.41 (SD = 6.72). Similarly, among those that made any change to a relative's disease status in their pedigree, the average number of relatives with a disease status change per pedigree was 4.62 (SD = 3.48). A total of 412 relatives had any change, while 194 had a disease change and 208 had an age change (current age, age of onset, age at death).



**Fig. 2** Types of pedigree changes after patient education. The bar graph represents the percent of the study sample pedigrees with specific types of changes. Nearly half of the pedigrees (n = 49) had some change after patient education. Numbers below represent mean (and SD) number of

changes per pedigree of affected pedigrees in each category and total number of relative changes in each category. For example, 49 pedigrees had any changes resulting in a mean of 8.41(SD = 6.72) changes per pedigree among pedigrees with any changes and a total of 412 relatives with changes

#### Changes in elements of pedigree contributing to high quality FHH

As previously described in Methods, MeTree automatically meets 5 of 8 criteria for a high quality pedigree. We examined the remaining three criteria. For each pedigree, a percentage of eligible relatives satisfying each criterion was calculated and then averaged to describe the mean percentage before and after receiving education (Table 2). In general, the average percentage of eligible relatives satisfying the criterion increased following education. In addition, the completeness of disease documentation improved as indicated by the increase in the percentage of relatives per pedigree (42 vs. 45 %  $p = 0.002$ ) with a named health condition, an increase in the number of conditions per pedigree (18.9 vs. 20.5  $p < 0.001$ ) and by the decrease in the percentage of relatives per pedigree (9 % vs. 6 %  $p = 0.01$ ) with no data entered (relatives with no diseases, age, or alive/dead status reported). These changes yielded an increase in the percentage of relatives that were considered high quality (meeting 1 or more of the 3 non-automatic criteria if eligible) between pre and post-test (89 vs. 91 %  $p = 0.02$ ). The impact of this is shown in Fig. 3, which represents the overall increase in the percentage of relatives per pedigree meeting high quality criteria following patient education. This effect is most pronounced when 80 % or more of the relatives in the pedigree are required to meet all 8 criteria for the pedigree to be considered high-quality.

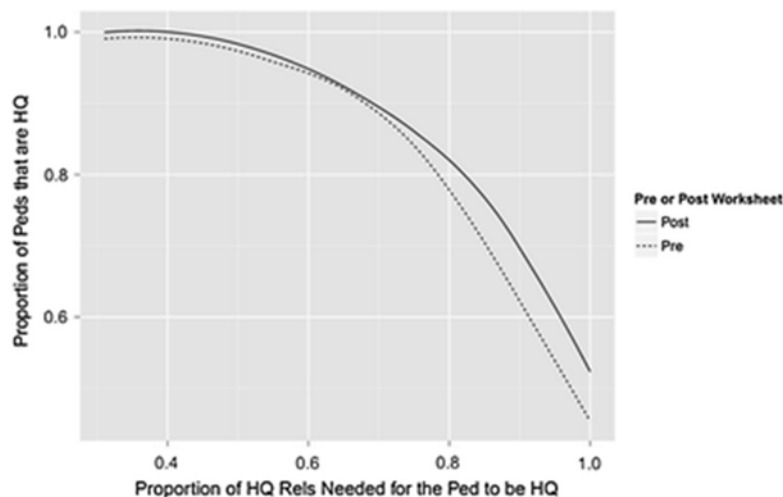
**Table 2** Percentage of family health history elements present before/after education

<b>Characteristic</b>	<b>Before</b>	<b>After</b>	<b>P value*</b>
Dead relatives who have age at death	81 %	84 %	0.02
Dead relatives with cause of death	87 %	91 %	0.02
Relatives who have age at onset	48 %	50 %	0.2
Relatives with some condition	42 %	45 %	<0.01
Relatives with no data	9 %	6 %	0.01
Number of conditions reported, mean (SD)	18.9 (11.0)	20.5 (11.7)	<0.01
High quality relatives in pedigree	89 %	91 %	0.02

For each pedigree, a percentage of eligible relatives satisfying each element was calculated. Numbers above represent an average of pedigree percentages before and after patient education

\*  $p$  value determined using Paired  $T$  test





**Fig. 3** Proportion of high-quality pedigrees versus proportion of high-quality relatives required. The figure illustrates the diminishing proportion of pedigrees that meet high-quality criteria as the proportion of high-quality relatives, those meeting all 8 criteria, required increases. The *horizontal axis* is the proportion of high-quality relatives required for the pedigree to be considered high-quality. The *vertical axis* is the proportion of pedigrees that are considered high quality. The post education pedigree demonstrates a greater proportion of pedigrees that are considered high-quality, with a pronounced effect above a 0.8 threshold

#### Changes in risk stratified care recommendations for pilot conditions

Because of the way risk is assessed in preventive care guidelines for clinical decision support conditions (breast, ovarian, and colon cancer, hereditary cancer syndromes, and thrombosis), pedigree changes that could trigger a change in risk stratified preventive care recommendations were disease status and change in age of disease onset. Among 99 participants, 42 % made changes to disease status and 18 % to age of disease onset. Combined, 43 participants made a change in at least one of these two criteria resulting in 43 % with a potential recommendation change. Of these, 12 of 43 (28 %) participants received recommendation changes. See Table 3 for details regarding which recommendations were changed and how frequently. Specifically, 4 received new recommendations to undergo genetic counseling, and 6 received new recommendations for colon cancer screening.

**Table 3** Changes in genetic counseling or screening recommendations (Pre → Post)

Recommendation	Yes → No	No → Yes	Total number of post “Yes” Recs
Breast cancer screening rec*	0	0	2
Colon cancer screening rec	4	6	30
Genetic counseling rec	2	4	24
Total changes	6	10	

\* *rec* recommendation. There were two pedigrees with a recommendation for breast MRI that did not change from pre-test to post-test. Four pre-test recommendations for colon cancer

screening were removed at post-test while six of the total recommendations for screening at post-test (20 %) would have been missed by pre-test alone

## **Discussion**

FHH, one of the strongest predictors of disease risk, is an important component of patient care that facilitates risk stratification for non-routine screening procedures, diagnostic testing and referral to genetic counseling in multiple common diseases. Yet, absent or insufficient reimbursement, competing clinical demands, inadequate training in gathering/interpreting FHH, and limited patient knowledge of their FHH mitigate its full potential in patient care delivery. Using a previously developed and validated patient facing software application, we sought to examine the influence of patient education on the quantity of data entered, the quality of the FHH generated (which affects the ability to perform risk stratification), and its impact on the risk stratified screening recommendations the patient met criteria for.

We found a substantial number of changes between pre and post education pedigrees. The types of changes were varied and included changes in diseases as well as age of onset which are critical in generating risk stratified recommendations. We also noted improvements in multiple elements of FHH required for adequate risk stratification and a significant overall increase in the percentage of relatives in each pedigree meeting high quality criteria for risk stratification. In addition, patients did obtain and review their own medical files in order to update their personal history in MeTree. Together, these findings may indicate a willingness on patients' part to become more active members in their healthcare by seeking additional information and consulting with others when needed; particularly when they are made aware of the endeavor's importance and how to accomplish it effectively. This is an important step towards meeting the goals of shared decision making and patient activation.

Remarkably, more than a quarter of the changes that could potentially change recommendations resulted in actual changes to recommendations for genetic counseling referral or surveillance. Collectively, these results suggest that receipt of patient education regarding who, how, and what to collect when obtaining FHH yields a clinically meaningful difference in the provision of care for patients. Furthermore, patient education enhances the adequacy of FHH, increasing the accuracy of clinical decision support and appropriate care recommendations. We liken an inadequate FHH to performing a diagnostic test only to receive indeterminate results. Patient education reduces the percentage of indeterminate results in using FHH.

This study is limited in several aspects. First, the sample size was limited to 100 participants with follow up data for 99 participants. While the sample exhibited comparable demographics to the parent study and the larger clinic population, we could not eliminate the potential for unmeasured differences in the study sample which may have contributed to differences in the pre and post MeTree sessions. We also acknowledge that this sub-study and the parent study population may be more educated than the national population, potentially limiting

generalizability of our results. Second, the study did not include a traditional control group with patients who did not receive any education. To address the possibility of the potential for test-maturation bias, we examined this issue further in secondary analysis of attributes that should not change with testing (number of siblings) and with attributes that should only change with patient education (number of relatives with number of polyps data). These results suggest changes are secondary to patient education and not due to a second exposure to MeTree. However, alone they cannot be considered confirmatory. Finally, although MeTree collects FHH for 48 diseases, real-time clinical decision support was only active for five pilot conditions. As a greater number of conditions are activated with clinical decision support, we would anticipate the number of changes seen in the pedigrees to result in a greater influence on additional risk stratified screening and testing.

In conclusion, patient education significantly improves FHH collection and subsequent risk stratification. Patient education yields important changes in actionable evidence-based care recommendations. It may also serve to activate patients and make them partners in their own healthcare. Thus, patient education concerning FHH is imperative regardless of the method utilized to collect it. However, the combination of patient education and a patient facing FHH collection tool optimize the wealth of clinical information utilized in providing non-routine screening procedures, diagnostic testing, and referral to genetic counseling for multiple common diseases. Take-home educational materials and a patient self-administered software application maximally leverage the generalist's resources in discussing recommendations within multiple complex competing clinical demands encountered during care delivery.

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## *Conflict of interest*

None.

## *Electronic supplementary material*

The online version of this article (doi:[10.1007/s10689-014-9701-z](https://doi.org/10.1007/s10689-014-9701-z)) contains supplementary material, which is available to authorized users.

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