Familial Risk for Common Diseases in Primary Care

The Family Healthware™ Impact Trial

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Context: Family history is a risk factor for many common chronic diseases, yet it remains underutilized in primary care practice.

Background: Family Healthware™ is a self-administered, web-based tool that assesses familial risk for CHD; stroke; diabetes; and colorectal, breast, and ovarian cancer, and provides a personalized prevention plan based on familial risk. The Family Healthware Impact Trial evaluated the tool.

Design: In this cluster RCT, participants completed baseline and 6-month follow-up surveys. The intervention group used Family Healthware directly after the baseline survey. Controls used the tool after completing the follow-up survey.

Setting/participants: Patients aged 35–65 years with no known diagnosis of these six diseases were enrolled from 41 primary care practices.

Main outcome measures: The prevalence of family-history–based risk for coronary heart disease (CHD); stroke; diabetes; and colorectal, breast, and ovarian cancer was determined in a primary care population.

Results: From 2005 to 2007, 3786 participants enrolled. Data analysis was undertaken from September 2007 to March 2008. Participants had a mean age of 50.6 years and were primarily white (91%) women (70%). Of the 3585 participants who completed the risk assessment tool, 82% had a strong or moderate familial risk for at least one of the diseases: CHD (strong=33%, moderate=26%); stroke (strong=15%, moderate=34%); diabetes (strong=11%, moderate=26%); colorectal cancer (strong=3%, moderate=11%); breast cancer (strong=10%, moderate=12%); and ovarian cancer (strong=4%, moderate=6%). Women had a significantly ($p<0.04$) higher familial risk than men for all diseases except colorectal and ovarian cancer. Overweight participants were significantly ($p\leq0.02$) more likely to have a strong family history for CHD, stroke, and diabetes. Older participants were significantly ($p\leq0.02$) more likely to report a strong family history for CHD and stroke as well as colorectal and breast cancer.

Conclusions: This self-administered, online tool delineated a substantial burden of family-history–based risk for these chronic diseases in an adult, primary care population.

Trial registration: NCT00164658.

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Introduction

Coronary heart disease (CHD), stroke, diabetes, and cancer account for approximately 60% of total deaths each year in the U.S.[1,2] Family history influences the risk of developing these multifactorial diseases. The relative risk for CHD; stroke; diabetes; and colorectal, breast, and ovarian cancer is approximately doubled if one first-degree relative is affected in middle age, and some family-history patterns carry a much stronger risk.[3–10] Knowledge of family-health history can guide risk-specific disease prevention, potentially reducing the burden of these chronic diseases.[11,12] Yet, owing to constraints on time, competing demands, and the complexity of familial-risk interpretation, systematic collection and assessment of detailed family-health histories rarely are done in primary care practice.[13–18] Thus, the effects are mostly unknown of systematically identifying and communicating the familial risk of disease to healthy adults. Likewise, data are very limited on the prevalence of family-health history that increases patients' risk for common chronic diseases.[19–21]

As part of a public health initiative to evaluate the use of family-health history for risk assessment and prevention, the CDC created Family Healthware™, an interactive online tool that provides personalized familial-risk assessments based on an individual's family history of six common chronic diseases as well as prevention plans with recommendations for lifestyle changes and screening tests. The tool systematically collects and records family-history information for CHD; stroke; diabetes; and colorectal, breast, and ovarian cancer by specifically asking about the occurrence of each disease (yes, no, don't know) as well as the age of disease onset (in 5-year increments) in every first- and second-degree relative. The software analyzes the user input, generating a three-tiered family-history–based risk assessment (see online appendix at www.ajpm-online.net) for each disease based on algorithms assessing the number of affected relatives, age at onset, and related conditions (i.e., both breast and ovarian cancer in the same lineage).[12,22] In general, a weak familial risk is assigned to users with only one second-degree relative with late-onset disease or no family history of the disease. Moderate familial risk is consistent with either one first-degree or two second-degree relatives with late-onset disease. Strong familial risk is assigned when there is a first-degree relative with early-onset disease, multiple affected relatives, or a disease pattern suggesting a hereditary syndrome. The user's risk behaviors, including smoking, diet, physical activity, alcohol use, aspirin use, and current screening history are used to tailor risk-based preventive health messages. For example, a woman aged 35 years with a strong familial risk who had never had a mammogram would receive the message *You may benefit from breast cancer screening at a younger age than is usually recommended. Talk to your health professional.* Details about the development and features of Family Healthware have been described elsewhere.[22]

In 2003 the CDC selected three academic centers to evaluate the clinical utility of this new tool: Evanston Northwestern Healthcare (ENH); the University of Michigan; and Case Western Reserve University (CWRU) with the American Academy of Family Physicians' (AAFP) National Research Network (NRN). The goal of the Family Healthware Impact Trial (FHITr) was to determine whether providing tailored family-health history messages influenced the adoption of healthy behaviors, recommended health screenings, and family and provider communication related to the six diseases. Additionally, the study aimed to measure the prevalence of three levels of family-history–based risk for the six diseases (weak, moderate, strong) among adults without a personal history of any of these diseases. This report presents the study methods and prevalence of family history for each of the six diseases in this primary care population.

Methods

Study Design

The FHITr used a practice-based, cluster-randomized design. Primary care practices were randomized to either the intervention or the control arm. In the intervention arm, participants first completed an online baseline survey, followed by Family Healthware, and subsequently received personalized risk assessment and prevention messages generated by the tool. The control group completed the baseline survey and received standard prevention messages about screening and healthy lifestyle choices recommended for the general population for the six diseases included in the tool. Approximately 6 months later, both the intervention and control groups completed a follow-up survey. The control group then also completed Family Healthware to enable comparisons not only between the intervention and control groups but also among familial-risk levels.

Pretest and Posttest Surveys

A computer-administered baseline survey was developed that measured demographics, health status, use of medical services, screening behaviors, lifestyle choices, and health beliefs. Health status was measured by the 12-item Short Form Health Survey.[23] Items assessing health behaviors were based on previously validated items from population-based studies.[24,25] Health beliefs were based on a conceptual model that incorporated elements of prevailing health behavior theory.[26–30] The assessment of perceived risk, perceived severity, worry, perceived control, self-efficacy, and response efficacy for each disease was based on single items to reduce responder burden.[26] The intent to adopt healthy behaviors and reduce unhealthy behaviors in the future was measured using a modified stages-of-change model,[28–30] because discrete behavior-change outcomes, such as an increase in exercise or the adoption of mammography screening, might not be captured

in the 6-month follow-up time. In addition, family-history communication patterns (among family members and physicians) were assessed, using an instrument developed by the investigative team. Participants were asked if they had talked with specific family members or any medical care provider about their family-health history, and then asked to indicate whether they had discussed particular topics pertaining to the risk and fear of getting the six diseases, medical screening, lifestyle changes, and genetic testing. Participants were also asked about potential barriers to the discussion of family-health history. Local experts at each site piloted questions for face validity. The questionnaire data-collection process was piloted at each site by people meeting the study criteria. The follow-up survey was modeled after the baseline survey to assess changes over time. The University of Michigan and CWRU–AAFP NRN sites also created a survey for healthcare providers to assess visit characteristics, preventive services, and referrals.

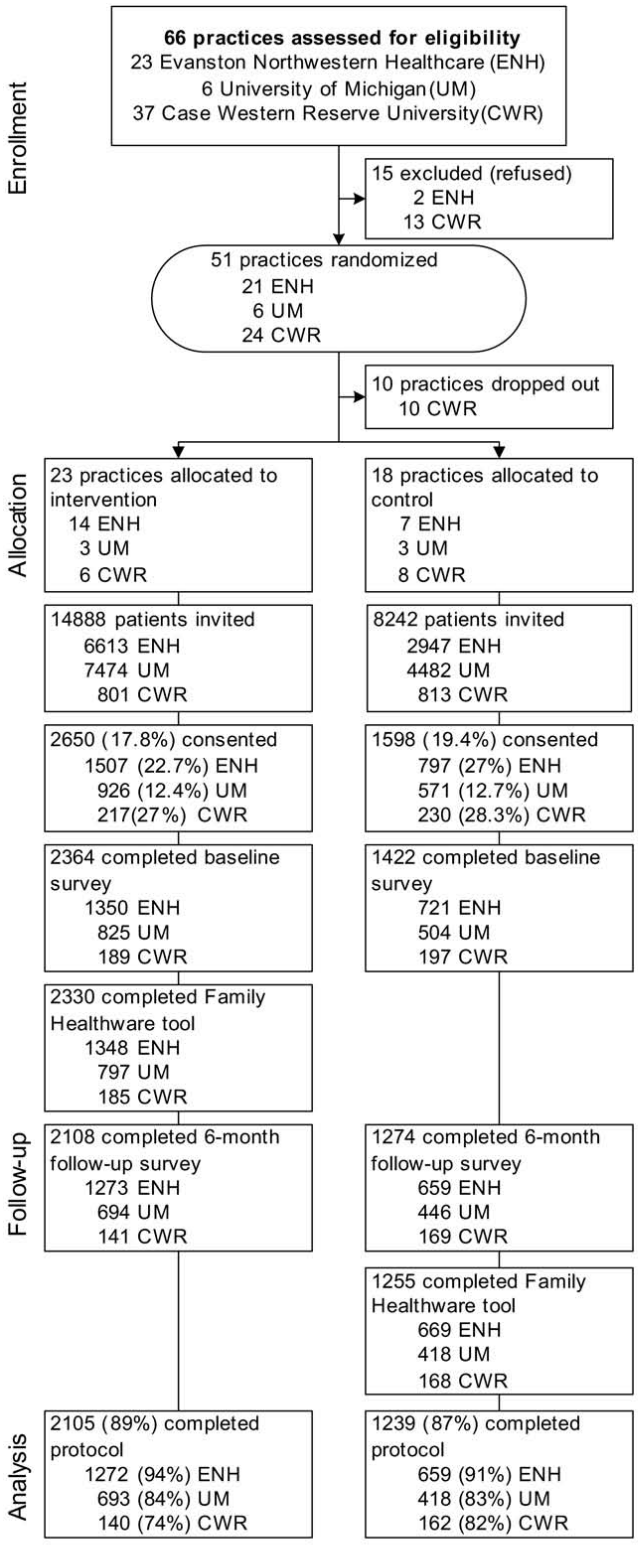
Participants and Recruitment

Researchers from each site recruited primary care practices affiliated with their organizations (ENH, the University of Michigan, CWRU–AAFP NRN). Within sites, each practice was randomly assigned to either the intervention or control arm, using site-specific randomization schemes. While essential aspects of study recruitment and consent were similar, site-specific differences are shown in Table 1. The 41 participating practices, including 187 participating clinicians in 13 states (Figure 1), enrolled patients at differ-

Table 1. Protocol details by site

	ENH	CWRU	UM
Practice locations	Hospital-based medical group and affiliates of Evanston Northwestern Healthcare (Chicago suburbs)	Primary care research network (community practices in 11 states: CA, CT, FL, GA, MT, NC, NJ, NV,OH, OR,VA)	Primary care clinics affiliated with University of Michigan Health System (Ann Arbor MI area)
Practice types	Internal medicine (21); family medicine (17); obstetrics/gynecology (4)	Family medicine (14)	Internal medicine (1); family medicine (5)
Practice randomization	Intervention/control 2:1	Intervention/control 1:1	Intervention/control 1:1
Patient identification	Upcoming scheduled office visit; EMR or paper chart review for age criteria	Upcoming scheduled office visit; record review for age criteria; systematic procedure for random selection if more eligible patients than could be invited in a given week	Existing patient lists; no scheduled visit required; EMR review for age criteria; physician review of patient invitation list
Patient recruitment: initial contact	Mailed invitation letter from physician, informed-consent document, opt-out postcard	Mailed invitation letter from physician, including study ID and login password; web portal for online consent	Mailed invitation letter from physician; opt-in postcard
Patient recruitment: reminders	Three telephone calls at 2-week intervals	One phone call, time permitting	Second invitation letter after 2–4 weeks
Patient recruitment: consent	On receipt of signed consent document, patient was mailed further info, study ID, and login password	Online consent followed by signed consent at time of scheduled visit. After December 2006, only online consent required	On receipt of opt-in postcard, informed-consent document mailed. On receipt of signed consent, patient was mailed further info, study ID, and login password
Survey and Family Healthware™ completion	Online at study website or telephone interview	Online at study website or MD office computer	Online at study website or Telephone interview
Delivery of printed prevention messages	In person at scheduled appointment (copy to MD at patient request)	In person at scheduled appointment (copy to patient and MD)	Mailed or e-mailed to patient; patient asked to bring to MD at next visit
Questionnaires for physicians	Not applicable	After patient appointment, paper questionnaire to measure visit characteristics, preventive services, and referrals; intervention-group physicians answered additional questions evaluating the utility of the Family Healthware™ report	All study participants given surveys to give to any healthcare provider seen after baseline assessment was completed in order to measure visit characteristics, preventive services, and referrals

CWRU, Case Western Reserve University–American Academy of Family Physicians' National Research Network; EMR, electronic medical record; ENH, Evanston Northwestern Healthcare; UM, University of Michigan Health System (Ann Arbor MI area)



ent times throughout the recruitment period. Participants were healthy adults aged 35–65 years. Exclusion criteria included a personal history of CHD, diabetes, stroke, or any cancer other than nonmelanoma skin cancer; the inability to speak or read English; and known pregnancy. All sites systematically identified potential participants from the practices' patient records (Table 1). Patients received invitation letters signed by their primary care physicians. Individual protocols were approved in 2004 by IRB's at all three centers, and a combined protocol was approved by the CDC's IRB. Recruitment took place from November 2005 to March 2007.

Data Collection

The survey instruments and the Family Healthware tool were accessed through a dedicated website; the study databases were housed in two SQL servers maintained by ENH. Site coordinators monitored progress, using management databases created by ENH and AAFP. Subjects could log on at any time using unique usernames and passwords that enabled them to complete the instruments over multiple sessions, if needed. Automated time stamps recorded only the start of input and the generation of the Family Healthware report; thus, completion time for the tool was calculated only for those who finished in <60 minutes. It was assumed that longer time intervals represented individuals who did not complete the input in one consecutive sitting, because pilot testing indicated a mean input time of 20 minutes even for the largest families.

For usability reasons, surveys were designed with automated skip patterns. Most entries were mandatory to minimize missing data. Almost all participants (91%) completed all instruments online through the website or a computer in their doctor's office, although participants could also respond by telephone with data entered online by study personnel. For the most part, the latter occurred because of the time constraint of completing the Family Healthware tool before a participant's provider appointment instead of a reluctance to go online. Online participants received Family Healthware risk levels and messages instantly on-screen, but all participants were either mailed or given printed reports. Participants received a $10 incentive after completing each survey.

Main Outcome Measures and Analysis

This report presents characteristics of the study participants and the distributions of the familial-risk classification for each disease. Comparisons of these distributions were made on

	Intervention				Control			
	ENH	UM	CWR	Total	ENH	UM	CWR	Total
Practices	14	3	6	23	7	3	8	18
Median # physicians	5	10	1	5	5	9	1	2.5
Range	1–9	7–19	1–3	1–19	2–6	7–18	1–4	1–18
Median # patients enrolled	108	317	13	108	107	183	20	72
Range # patients enrolled	9–127	133–374	5–118	5–374	55–143	114–208	2–66	2–208

Figure 1. Family Healthware™ impact trial enrollment and retention
Recruitment percentage: Number of individuals consented/number of individuals invited
Retention percentage: Number of individuals who completed all study instruments/number of individuals who completed baseline survey

Table 2. Demographics of study participants by study arm

	Intervention arm n=2364 n (%)[a]	Control arm n=1422 n (%)[a]
Gender		
Male	688 (29)	460 (32)
Female	1676 (71)	962 (68)
Age (years)		
M (SD)	50.3 (8.4)	51.1 (8.0)
Are you Hispanic or Latino?		
Yes	58 (2)	29 (2)
Race		
White or Caucasian	2134 (90)	1320 (93)
Black or African American	87 (4)	35 (3)
Asian	70 (3)	31 (2)
Native Hawaiian or other Pacific Islander	2 (0.1)	2 (0.1)
American Indian, Alaska native	2 (0.1)	1 (0.1)
Other	69 (2.9)	33 (2.3)
Marital status		
Single, never married	203 (9)	96 (7)
Married/living with partner	1857 (79)	1135 (80)
Formerly married	304 (12)	191 (13)
Level of education		
≤Grade 11	22 (1)	8 (0.6)
High school graduate	189 (8)	115 (8)
Some college or technical school	453 (19)	274 (19)
College graduate	1700 (72)	1025 (72)
Annual household income ($)[b]		
<25,000	91 (4)	41 (3)
25,001–50,000	320 (16)	151 (12)
50,001–75,000	402 (19)	228 (18)
>75,000	1262 (61)	834 (66)
Do you currently have any kind of health insurance?		
Yes	2276 (96)	1380 (97)
Number of visits to doctor in last year		
M (SD)	4.6 (5.7)	4.7 (5.7)
BMI		
M (SD)	27.4 (6.2)	27.2 (5.7)
It is important for my own health to know if diseases like cancer, diabetes, stroke, or heart disease run in my family.		
Disagree	124 (5.2)	75 (5.3)
Neither agree or disagree	56 (2.4)	31 (2.2)
Agree	2184 (92.4)	1316 (92.5)

Note: The comparisons are between the study arms for each variable and are adjusted for clustering effects. There were no significant differences found for any of the variables.
[a]Unless otherwise noted
[b]Twelve percent not reported

gender, age, smoking status, BMI, and type of medical care practice. Generalized estimating equation methods were used to adjust for the clustering by practice in all comparisons among groups. Data analysis was conducted from September 2007 to March 2008 using SAS version 9.1.

Results

Demographics of the Study Population

While 4248 subjects were enrolled, 3786 actually completed the baseline survey. Overall the study had 18% recruitment, 89% retention from time of consent to completion of the baseline survey, and 88% retention from baseline to follow-up (Figure 1).

The study population was mostly white (91%) women (70%) who were married (76%), insured (97%), and of relatively high SES, with a mean age of 50.6 years, as summarized in Table 2. (Full demographic data are available as Appendix B online at www.ajpm-online.net.) The distribution of participants by practice type was family practice, 1834 (48%); internal medicine, 1485 (39%); and obstetrics/gynecology, 467 (12%). There were no significant demographic differences between control and intervention groups or between online and telephone users.

Familial-Risk Levels in the Primary Care Population

Family Healthware was completed by 3585 participants. The mean completion time for a convenience sample of 1170 consecutive participants was 19.6 minutes (range: 5.5–59.6; median: 17.0; mode: 9.63). The distribution of familial-risk levels for each disease is summarized in Table 3. For both genders, CHD had the highest percentage in the strong-risk category, followed by stroke; diabetes; and breast, ovarian, and colorectal cancer. Overall, 82% of participants had a strong or moderate risk for one or more of the six diseases.

Women's reported family histories placed them at significantly higher familial risk than men for all diseases except colorectal and ovarian cancer ($p<0.04$), although men reported *don't know* more often when prompted for the disease history of their relatives ($p<0.001$) For both genders, the prevalence of *don't know* responses across all relatives ranged from 25% (breast and ovarian cancer) to 28% (CHD). This response was significantly more likely in second-degree versus first-degree relatives and for male versus female relatives ($p<0.001$) for all diseases. Overweight participants (BMI≥25) were significantly more likely than normal-weight participants to have a strong familial risk for CHD, stroke, and diabetes ($p\leq0.02$). Those aged ≥50 years were significantly more likely to be classified in the strong-risk category for CHD, stroke, and colorectal and breast cancer than younger participants ($p\leq0.02$). There was no significant difference in familial-risk classification due to smoking status or recruitment practice type.

Discussion

This study's results demonstrate that there is a substantial burden of family-history–based risk among unaffected adults aged 35–65 years who are seen in primary care practices. Although estimates of the prevalence of

Table 3. Stratification of familial risk for common diseases as calculated by the Family Healthware™ risk assessment tool (n=3585)

	Familial risk						
	Weak		Moderate		Strong		
	Men *n* (%)	Women *n* (%)	Men *n* (%)	Women *n* (%)	Men *n* (%)	Women *n* (%)	*p*-value[a]
Coronary heart disease	494 (46)	955 (38)	265 (24)	673 (27)	321 (30)	877 (35)	0.010
Stroke	620 (57)	1232 (49)	311 (29)	891 (36)	149 (14)	382 (15)	0.007
Diabetes	695 (64)	1543 (62)	294 (27)	651 (26)	91 (8)	311 (12)	0.040
Colorectal cancer	938 (87)	2146 (86)	116 (11)	294 (12)	26 (2)	65 (3)	0.382
Breast cancer	883 (82)	1906 (76)	109 (10)	335 (13)	88 (8)	264 (11)	0.001
Ovarian cancer	984 (91)	2258 (90)	48 (4)	150 (6)	48 (4)	97 (4)	0.380

[a]The comparisons of percentages in each risk level are between men and women and are adjusted for clustering effects (*p*-values refer to the distribution across risk levels).

family history of common diseases have been made from national surveys,[31–33] these data represent the first based on more-detailed family histories that have been collected in primary care settings. These data will be invaluable in planning, implementing, and analyzing future studies on family-health history in primary care.

Accuracy of Estimates and Variability Among Subgroups

Because Family Healthware risk algorithms depend on reported disease in both first- and second-degree relatives, this study's prevalence figures may underestimate actual familial risk. The accuracy of self-report of familial disease has been examined in a number of studies[34–37] using various standards of reference such as medical records, death certificates, and confirmation by relatives. In general, specificity is high and sensitivity is somewhat lower, indicating that individuals are better at reporting the absence of disease in relatives than the presence of a specific type of disease. Sensitivity has been shown to be lower in second-degree relatives compared to first-degree relatives, a finding in agreement with the preponderance of *don't know* responses for second-degree relatives in this study. In addition, most studies examining the accuracy of self-reported family history have been done in populations affected by the disease of interest, whereas this study's participants were unaffected by any of the six assessed diseases. While this might result in some underreporting of affected relatives due to decreased salience, several case-control studies have shown little difference in accuracy between affected and unaffected informants.[36,38,39]

Women had higher calculated family risks than men for all diseases except colorectal and ovarian cancer. However, the percentage of subjects stratified by Family Healthware into strong- or moderate-risk categories was lower for these two cancers than for the other diseases, and therefore the power to detect gender differences may have been limited. This finding may be due to recall or informational bias, with women reporting, actually knowing more, or both, about the disease histories of family members. Other studies have compared men's and women's accuracy in reporting a family history of cancer. Some studies[39–41] showed no difference, while others[38,42–44] showed that women reported their family history more accurately than men. Theoretically, for unaffected individuals, family history should not vary by gender. If men do underreport family history when using a screening tool such as Family Healthware, the actual prevalence of the familial risk may be higher than reported here. Verification of family histories was beyond the scope of this study.

Although the risk algorithms did not include any personal risk factors such as age, it was found that adults aged ≥50 years had higher familial risks than their younger counterparts for most diseases. Studies of age as a determinant of family-history accuracy have had varying results.[37,45] For adult-onset diseases, older individuals may be more likely to have affected first- and second-degree relatives than younger people and may be better sources for familial-risk assessment when using tools that do not include more-distant relatives. However, prevention interventions may be more effective in younger individuals, pointing to a need to encourage families to communicate about familial risk.

A novel although not unexpected finding is the difference in risk classification for overweight participants. The relationship of being overweight to a family history of diabetes and cardiovascular disease reflects the consequences of genetic susceptibilities, shared environment, and common behaviors,[46] consistent with the familial aggregation of metabolic syndrome. In contrast, smoking status is not associated with familial-risk classification for the diseases assessed in this study population.

The validity of the risk-stratification algorithms is essential to the overall utility of the Family Healthware tool. Although population-based data to validate familial-risk algorithms are few, several recent studies[32,33,47] have assessed the performance of risk-stratification rules similar to those used in Family Healthware. Table 4 shows that they have fairly good agreement with this study's

Table 4. Prevalence of familial risk in selected studies

Study	Disease	Ascertainment	*n*	Familial risk		
				Weak (%)	Moderate (%)	Strong (%)
Scheuner (2006)[32]	CHD	HealthStyles 2003	4,035	56.8	11.7	31.5
FHITr	CHD	Primary care	3,585	40.6	26.41	32.9
Hariri (2006)[47]	Diabetes	HealthStyles 2004	4,345	65	19	16
Valdez (2007)[33]	Diabetes	NHANES 1999–2004	16,388	70	23	7
FHITr	Diabetes	Primary care	3,585	61	28	11

CHD, coronary heart disease; FHITr, Family Healthware™ impact trial; NHANES, National Health and Nutrition Examination Survey

prevalence estimates. The FHITr prevalence of strong familial CHD risk is similar to the Scheuner study,[32] although the current study's population has a higher percentage in the moderate-risk group. The FHITr prevalence of strong familial diabetes risk lies between the two existing studies,[33,47] but again, the prevalence of moderate risk is higher. While it is possible that an active primary care population might have a higher family-history burden than the general population, further validation studies will be needed to replicate these findings.

Limitations

This study provides a unique insight into the distribution of family-history–based risk for six common diseases in primary care practices. The observation that almost all FHITr participants understand that family history is a risk factor for disease and believe that knowing their family history is important for their own health is not necessarily evidence that this sample had self-selected for interest in family history. In a national study[48] about awareness of family history, 96% of survey respondents reported that knowing their family history was important for their own health. The limited diversity of this study's population, racially and ethnically, limits the generalizability of results from the FHITr. Study participants were highly educated patients with health insurance who were, for the most part, able to use computers to access the study materials online. Data are not available to compare the race, ethnicity, educational attainment, or health-insurance status of patients invited versus those who participated. Replication in more-diverse populations is needed.

Although personal risk factors such as smoking, diet, physical activity, and BMI are incorporated in the tailored messaging, the Family Healthware risk algorithms do not include these factors. In addition, other established risk factors are not included, such as the biopsy history incorporated in the Gail model[49] for breast cancer, cholesterol levels for CHD, and even family-history details associated with hereditary colorectal cancer (polyps, hereditary nonpolyposis colorectal cancer–associated endometrial cancer). These limitations can be addressed in future versions of the tool.

Finally, Family Healthware provides familial-risk assessment for men related to breast and ovarian cancer. Obviously, this is not always relevant to a male individual's personal risk, but it is important to female family members. It is not clear how receptive men or their healthcare providers may be to messages about preventing these two cancers.

Familial-Risk Stratification for Screening and Prevention

Prevention measures exist for all of the diseases assessed, and familial-risk stratification can identify those people most likely to benefit from targeted preventive strategies. One impetus for assessing risk for multiple diseases in Family Healthware was the recognition that the same risk-reducing behaviors contribute to preventing a variety of chronic diseases. However, the adoption of Family Healthware or other similar tools will be limited until clinical benefits can be shown. A few population-based studies have found that having a family history of a chronic disease was associated with a greater awareness of risk and reported risk-reducing behaviors,[50–52] but data from clinical practice are very limited.

Computerized family-history tools that include sophisticated risk assessment algorithms are fast being developed.[22,53–59] The FHITr trial has demonstrated that a segment of the primary care population is both interested in family-health history (the study retention was high) and able to easily use a computerized risk assessment tool outside of the clinical setting (completion time was quite modest). More validation studies in diverse populations are critically needed before the widespread dissemination of these tools.

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Suzanne O'Neill and Mack Ruffin, principal investigators, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. The data, in part, were presented as abstracts at The American Society of Human Genetics annual meeting in 2007, the National Prevention and Health Promotion Summit in 2007, and the Sixth American Association for Cancer

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Appendix

Supplementary Data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.amepre.2009.03.002.