

Family History Assessment Impact on Disease Risk Perceptions

Catharine Wang, PhD, MSc, Ananda Sen, PhD, Mack T. Ruffin IV, MD, MPH, Donald E. Nease Jr, MD, Robert Gramling, MD, DSc, Louise S. Acheson, MD, MS, Suzanne M. O'Neill, MA, MS, PhD, Wendy S. Rubinstein, MD, PhD, for the Family Healthware™ Impact Trial (FHITr) Group

Background: Family Healthware™, a tool developed by the CDC, is a self-administered web-based family history tool that assesses familial risk for six diseases (coronary heart disease; stroke; diabetes; and colon, breast, and ovarian cancers) and provides personalized prevention messages based on risk. The Family Healthware Impact Trial (FHITr) set out to examine the clinical utility of presenting personalized preventive messages tailored to family history risk for improving health behaviors.

Purpose: The purpose of this study was to examine the impact of Family Healthware on modifying disease risk perceptions, particularly among those who initially underestimated their risk for certain diseases.

Design: A total of 3786 patients were enrolled in a cluster-randomized trial to evaluate the clinical utility of Family Healthware.

Setting/participants: Participants were recruited from 41 primary care practices among 13 states between 2005 and 2007.

Main outcome measures: Perceived risk for each disease was assessed at baseline and 6-month follow-up using a single-item comparative risk question. Analyses were completed in March 2012.

Results: Compared to controls, Family Healthware increased risk perceptions among those who underestimated their risk for heart disease (15% vs 9%, $p < 0.005$); stroke (11% vs 8%, $p < 0.05$); diabetes (18% vs 11%, $p < 0.05$); and colon cancer (17% vs 10%, $p = 0.05$) but not breast or ovarian cancers. The majority of underestimators did not shift in their disease risk perceptions.

Conclusions: Family Healthware was effective at increasing disease risk perceptions, particularly for metabolic conditions, among those who underestimated their risk. Results from this study also demonstrate the relatively resistant nature of risk perceptions.

Trial registration: This study is registered at clinicaltrials.gov NCT00164658. (Am J Prev Med 2012;43(4):392–398) © 2012 American Journal of Preventive Medicine

Introduction

Family history is undisputedly one of the most important risk factors for common, chronic disease and has received widespread attention in recent years as an important genomic tool for preventive medicine and public health.^{1–7} The proportion of the population at elevated risk as a result of their family health history is sizable. Recent population-based studies have demonstrated that the burden of familial risk (i.e., having a moderate or strong familial risk) is approximately 29% for diabetes and 22% for cancers, including breast, ovarian, endometrial, prostate, and colorectal.^{8,9}

Compared to risk assessment via genomic testing, family history assessment has several advantages including lower cost, greater acceptability, and a reflection of shared

From the Department of Community Health Sciences (Wang), Boston University School of Public Health, Boston, Massachusetts; the Department of Biostatistics (Sen) and the Department of Family Medicine (Sen, Ruffin), University of Michigan, Ann Arbor, Michigan; the Department of Family Medicine (Nease), University of Colorado Health Sciences Center, Aurora, Colorado; the Schools of Medicine and Nursing (Gramling), University of Rochester, Rochester, New York; the Departments of Family Medicine and Community Health and Reproductive Biology (Acheson), Case Western Reserve University and Case Comprehensive Cancer Center, University Hospitals Case Medical Center, Cleveland, Ohio; the Department of Medicine (O'Neill), Feinberg School of Medicine, Northwestern University, Chicago, Illinois; and the National Center for Biotechnology Information (Rubinstein), NLM, NIH, Bethesda, Maryland

Address correspondence to: Catharine Wang, PhD, MSc, Department of Community Health Sciences, Boston University School of Public Health, 801 Massachusetts Avenue, Crosstown Center, 3rd Floor, Boston MA 02118. E-mail: clwang@bu.edu

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genetic and environmental risk factors.⁴ Moreover, family history is often associated with desired health behaviors, including cancer screening^{10,11} and self-reported changes in diet and exercise,^{9,12} suggesting that increasing people's awareness of their risk associated with family history may have important implications for motivating healthy behaviors.^{1,4}

Currently, family history assessment is underutilized in clinical practice. Medical chart audit studies have reported that approximately 20%–50% of patients at elevated disease risk based on their family history were undocumented as such.^{13,14} Barriers to the implementation and use of family history include the lack of time, effort, and skills needed for family history collection and interpretation.⁵ Public health efforts to overcome these challenges have focused on the development of both electronic and print-based family history tools to facilitate the process of documenting and interpreting family history.¹⁵

In 2004, the CDC developed Family Healthware™, a self-administered web-based family history tool that assesses familial risk for six common chronic conditions and provides personalized prevention messages based on risk.¹⁶ The Family Healthware Impact Trial (FHITr) is a cluster-randomized trial that set out to examine whether the provision of personalized prevention messages, based on family history risk for coronary heart disease; stroke; diabetes; and colon, breast, and ovarian cancers would result in changes in corresponding screening and lifestyle behaviors. Conceptually, the mechanism by which Family Healthware was predicted to influence health behaviors was its impact on modifying participants' cognitive perceptions, particularly perceptions of disease risk.¹⁷ Thus, it was hypothesized that by increasing awareness of people's heightened risk for disease based on their family history, these individuals would be more motivated to engage in protective behaviors to reduce their risk. Support for the behavioral motivation hypothesis comes from several models of health behavior^{18–20} as well as empirical evidence of the predictive temporal link between risk perceptions and subsequent behaviors.²¹

Results from the Family Healthware Trial (FHITr) to date have shown that approximately 82% of the study participants were identified as having elevated familial risk (i.e., moderate or strong risk because of their family history) for at least one of the six diseases included in the tool,²² with more than one third of participants at risk for three or more diseases. Perceptions of risk varied across the six diseases at baseline, with ratings of cancer risk perceptions significantly higher than those for the metabolic conditions included in the tool.²³ In spite of these differences across diseases, mean baseline ratings of perceived risk approximated the response option on the

measure representing “same as average” risk compared to others. This finding suggests that participants might be optimistically biased about their risk for disease, which is consistent with the well-documented health psychology literature to date.²⁴

The present study set out to accomplish the following: (1) document the percentage of individuals underestimating their risk for each disease included in the tool; (2) determine the impact of Family Healthware on shifting risk perceptions among individuals who underestimate their disease risk; (3) examine the extent to which impact of the tool varied across the six diseases; and (4) characterize, among underestimators, those who were more likely to shift their risk perceptions following the intervention.

Methods

Participants

A total of 3786 patients were enrolled in FHITr from 41 primary care practices among 13 states. None of the participants had a prior personal history of any of the six conditions. Patients were also ineligible for the study if they were unable to speak or read English, or had a known pregnancy.

Sample Recruitment and Randomization

The present study used a two-arm cluster-randomized design by primary care practices as previously described.²² Briefly, participating primary care practices were affiliated with one of the three academic sites: Evanston Northwestern Healthcare (ENH; now NorthShore University HealthSystem); the University of Michigan (U of M); and Case Western Reserve University (CWRU) with the American Academy of Family Physicians' National Research Network (AAFP NRN). Participants were identified from practice schedules and records according to site-specific protocols.²² Letters signed by patients' primary care physicians were sent to participants inviting them to participate in the study. Practices were randomly assigned to either the intervention or control arm, per site-specific randomization schemes. Individual protocols were approved in 2004 by the IRBs at the three participating academic centers. A combined protocol also was approved by the IRB at the CDC. Study recruitment took place between 2005 and 2007. The study CONSORT diagram is presented in Figure 1.

Intervention and Control Conditions

Participants in the intervention group completed a baseline survey, followed by Family Healthware assessment. Participants received personalized prevention messages delivered via mail, e-mail, or in person (print document), tailored to familial risk—weak, moderate, or strong—for each of the six conditions. Online participants also received these instantly, on-screen, following completion of the tool. In addition, messages were tailored on other variables including age, gender, reported health behaviors, and screening history.¹⁶ A family tree and information about the characteristics in one's family history that put the person at increased risk (if applicable) also were presented.

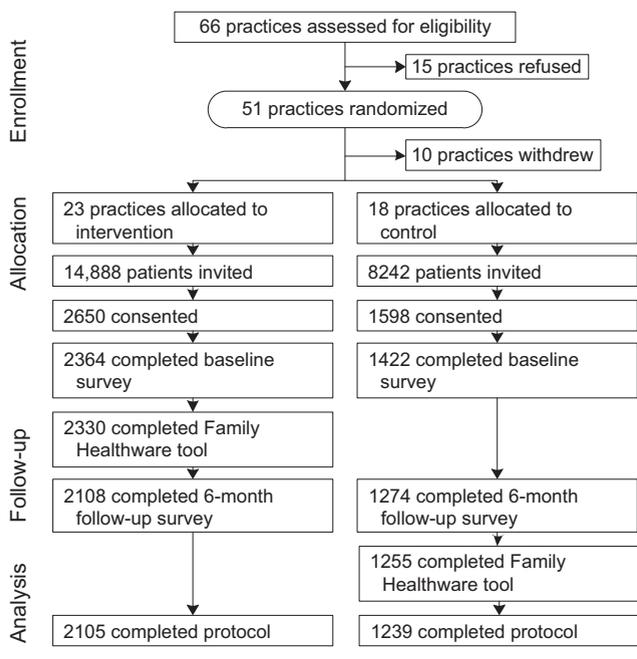


Figure 1. CONSORT flow diagram

In contrast, following completion of the baseline survey, participants in the control group received standard print messages (not personalized) about screening and lifestyle choices recommended for the general population via mail, e-mail, or in-person. Both groups completed a follow-up survey 6 months later, after which control group participants completed the Family Healthware tool and received personalized prevention messages. Additional details about the messages provided to intervention and control participants can be found elsewhere.¹⁷

Outcome Measures

Familial risk. Familial risk for each disease was assessed using the Family Healthware program, either at baseline for intervention participants, or following completion of 6-month follow-up for control participants. Familial risk was determined based on the self-reported health history for oneself and first- and second-degree relatives. Participants were categorized as having either a weak, moderate, or strong familial risk for each of the six conditions.

Weak familial risk: no family history or late-onset disease in only one second-degree or more distant relative from one or both sides of the family. Moderate familial risk: a first-degree relative with late-onset disease or two second-degree relatives from the same lineage with late-onset disease. Strong familial risk: a first-degree relative with early-onset disease, multiple affected relatives, or suspicion of a hereditary syndrome.¹⁶ In general, a moderate familial risk reflects an approximate twofold increase in risk over a weak familial risk; a strong familial risk is associated with about a three-fold or greater increase in risk.²⁵ For the current analyses, familial risk was dichotomized as either low risk (weak familial risk, which reflects average risk or lower on the tool) or high risk (moderate/strong familial risk, which reflects an increased, above-average risk level).

Perceived risk. Perceived risk for each of the diseases was assessed using a single item measured on a 5-point Likert-type scale

(much lower/lower/about the same/higher/much higher; all compared to average): *Compared to most people your age and sex, what would you say your chances are for developing _____?*^{24,26} For the current analyses, perceived risk was dichotomized as either low (much lower/lower/about the same as average) or high (higher/much higher than average) risk.

Analytic Plan

Descriptive statistics were used to report the baseline risk perceptions. Logistic regression models were used to examine change in risk perceptions over time. Specifically, for each disease, movement in risk perception for the underestimators (i.e., moved to high category at the end of study versus remaining low) was modeled. The main predictor of interest in the model was experimental group. Clustering by practice was accounted for by using a generalized estimating equations (GEE) approach. Analyses further controlled for age, BMI, smoking status, and study site by including them as independent variables in the regression model. For heart disease, stroke, diabetes, and colon cancer, gender was used as an additional predictor. Analyses were completed in March 2012.

Results

Demographic Characteristics

The demographic breakdown of study participants is provided in Table 1. The shows that the mean age of study participants was 50.6 years. The majority of participants were female, Caucasian, married, with a reported household income greater than \$75,000 per year. Overall, 82% of participants were categorized as having a moderate or strong familial risk for at least one of the six conditions.

Baseline Risk Perceptions Across Six Diseases

Based on familial risk as identified by Family Healthware, individuals were categorized as either being congruent, optimistically biased, or pessimistically biased in their risk perceptions. For example, those reporting risk perceptions that were consistent with familial risk were categorized as congruent (e.g., low perceived risk/low familial risk). Participants categorized as optimistically biased reported perceived risk as average or below average (low), when in fact, their familial risk was moderate/strong (high). The converse was true for those deemed pessimistically biased, who had elevated perceived risk estimates in comparison to familial risk.

Overall congruency between perceived and familial risk ranged from 53% to 90% depending on the disease (Table 2). Individuals were more likely to be optimistically biased than pessimistically biased, and tended to underestimate their disease risk for heart disease, stroke, and diabetes. This tendency was less evident for colon, breast, and ovarian cancer.

Table 1. Patient demographics, *n* (%) unless otherwise noted

Characteristics	Intervention arm (<i>n</i> =2364)	Control arm (<i>n</i> =1422)
Age, years (M)	50.3	51.1
Gender, female	1676 (71)	962 (68)
Race/Ethnicity		
Caucasian	2134 (90)	1320 (93)
African-American	87 (4)	35 (3)
Asian	70 (3)	31 (2)
Hispanic or Latino	58 (2)	29 (2)
Married/living with partner	1857 (79)	1135 (80)
Household income (>\$75,000)	1262 (61)	834 (66)
Smoker—current	185 (8)	108 (8)
Family history (moderate or strong)	<i>n</i> =2330 ^a	<i>n</i> =1255 ^a
Heart disease	1383 (59)	753 (60)
Stroke	1118 (48)	615 (49)
Diabetes	904 (39)	443 (35)
Colon cancer	315 (13)	186 (15)
Breast cancer	531 (23)	265 (21)
Ovarian cancer	223 (10)	120 (10)

^aSample size excludes participants without complete family history data.

Impact of Family Healthware on Disease Risk Perceptions

To examine the impact of Family Healthware on disease risk perceptions, analyses focused on those participants considered optimistically biased in their perceptions. Among risk underestimators, a greater percentage of individuals in the intervention arm increased in their disease risk perceptions at the 6-month follow-up (i.e., shifted perceived risk from low to high) compared to individuals in the control arm for the following diseases: heart disease (15% vs 9%, $p<0.005$); stroke (11% vs 8%, $p<0.05$); diabetes (18% vs 11%, $p<0.05$); and colon cancer (17% vs 10%, $p=0.05$; Table 3). Among women, shifts in risk perceptions did not differ between experimental arms for breast (18% vs 14%, $p=0.4$) or ovarian (8% vs 13%, $p=0.4$) cancer.

Notably, those individuals who shifted their risk perceptions tended to be younger, female, and have a higher BMI, compared to those who did not. Younger individuals had higher odds of increasing their risk perceptions for stroke and diabetes ($p's\leq 0.05$). Women and those

with a higher BMI were at higher odds of increasing their risk perceptions for heart disease, stroke and diabetes (all $p's<0.05$) compared to their counterparts.

Discussion

The Family Healthware Impact Trial (FHITr) set out to examine the clinical utility of presenting personalized preventive messages tailored to family history risk for improving health behaviors.¹⁷ As part of this effort, the present study provides data on the impact of the Family Healthware tool on disease risk perceptions over time. In particular, the current study focused on examining whether personalized feedback about an elevated familial risk for various conditions would be able to shift and increase comparative perceived risk estimates among individuals who initially reported they were at average or below-average risk.

Overall, FHITr participants were reasonably congruent in their disease risk perceptions, particularly for the three cancers included in the tool. Yet, a sizable proportion of individuals at elevated familial risk underestimated their risk for disease and were considered optimistically biased in their risk perceptions. Among these individuals, Family Healthware was successful at increasing perceived risk estimates for four of the six diseases for intervention participants compared to controls.

In particular, the tool had a greater impact on shifting risk perceptions for metabolic conditions, where congruency was considerably lower compared to cancers. The impact of the tool on increasing perceived risk for certain diseases yet not others was likely due in part to the prevalence of individuals in the sample who were classified at elevated familial risk for each disease. The base rates for “high” familial risk ranged from 10% to 60% depending on the disease, which subsequently had implications for calculations to derive congruency estimates. Diseases for which a higher proportion of individuals were classified as high risk may have resulted in either a greater likelihood of movement in risk perceptions or greater power to detect significant differences between experimental conditions.

Certain demographic characteristics predicted greater likelihood to change in some risk perceptions, including being younger, female, and having a higher BMI. Prior publications from the FHITr group reported that age (younger) and gender (female) were associated with greater baseline disease risk perceptions,^{23,27} and the present study suggests that these characteristics also may be associated with greater responsiveness to risk feedback. Similarly, familial risk feedback may have been more salient for individuals with higher BMI because of

Table 2. Perceived risk (6-month follow-up) for common diseases by familial risk, *n* (%) unless otherwise noted

Disease	Perceived risk low		Perceived risk high		Overall % congruent	<i>n</i> ^a
	Familial risk low	Familial risk high	Familial risk low	Familial risk high		
	Congruent	Optimistically biased (underestimator)	Pessimistically biased (overestimator)	Congruent		
Intervention arm						
Heart disease	838 (36)	968 (41)	109 (5)	415 (18)	54	2330
Stroke	1083 (46)	882 (38)	129 (6)	236 (10)	57	2330
Diabetes	1264 (54)	538 (23)	162 (7)	366 (16)	70	2330
Colon cancer	1893 (81)	169 (7)	122 (5)	146 (6)	88	2330
Breast cancer ^b	1152 (69)	193 (12)	98 (6)	212 (13)	82	1655
Ovarian cancer ^b	1324 (87)	98 (6)	58 (4)	42 (3)	90	1522
Control arm						
Heart disease	425 (34)	508 (40)	77 (6)	245 (20)	53	1255
Stroke	570 (45)	461 (37)	70 (6)	154 (12)	57	1255
Diabetes	717 (57)	260 (21)	95 (7)	183 (15)	72	1255
Colon cancer	1015 (81)	108 (9)	54 (4)	78 (6)	87	1255
Breast cancer ^b	602 (71)	98 (12)	53 (6)	96 (11)	82	849
Ovarian cancer ^b	685 (88)	53 (7)	22 (3)	20 (2)	90	780
Total sample						
Heart disease	1263 (35)	1476 (41)	186 (5)	660 (18)	53	3585
Stroke	1653 (46)	1343 (37)	199 (6)	390 (11)	57	3585
Diabetes	1981 (55)	798 (22)	257 (7)	549 (15)	70	3585
Colon cancer	2908 (81)	277 (8)	176 (5)	224 (6)	87	3585
Breast cancer ^b	1754 (70)	291 (12)	151 (6)	308 (12)	82	2504
Ovarian cancer ^b	2009 (87)	151 (7)	80 (3)	62 (3)	90	2302

^aSample size excludes participants without complete family history data or perceived risk data.

^bEstimates are based on women only.

their existing heightened risk for disease based on their weight.

Although Family Healthware had a significant impact on shifting some disease risk perceptions among underestimators, it is important to note that risk perceptions appear to be relatively resistant to change. In spite of receiving a detailed, tailored report outlining elevated disease risk based on family history, roughly 82%–92% of underestimators did not shift their risk perceptions accordingly at follow-up. It is possible that the presentation of risk and subsequent recommendations contained in the computerized reports lacked the intensity and strength to change perceived risk. Or, participants may have had difficulties processing the number of risks presented at the same time or understanding the implications of the personalized messages.¹⁵

The present study had several limitations including the over-representation of white, female, married, and insured primary care patients with relatively high SES. Caution is warranted when generalizing findings to other populations. In addition, intervention group participants were not verified at follow-up for having received the personalized preventive messages, which may serve as a possible threat to the internal validity of the study.

Perceived risk was assessed using a single-item measure in the current study. Actual risk for disease was based on family history assessment alone and did not include other risk factors that are relevant for disease. Thus, it cannot be determined from this study whether those categorized as “overestimators or pessimistically biased” would be considered incongruent in their risk perceptions because other factors within their personal medical

Table 3. Logistic regression models predicting shifts in risk perceptions (to elevated risk) among optimistically biased participants, OR (95% CI)

Predictors	Heart disease (n=1379)	Stroke (n=1252)	Diabetes (n=734)	Colon cancer (n=258)	Breast cancer (n=276)	Ovarian cancer (n=140)
Gender (ref: male)	1.53 (1.03, 2.28)*	2.00 (1.24, 3.22)**	1.56 (1.07, 2.27)*	1.12 (0.57, 2.21)	—	—
Age	0.99 (0.97, 1.01)	0.97 (0.97, 0.99)**	0.97 (0.95, 1.00)*	1.00 (0.96, 1.05)	0.96 (0.93, 1.00)	0.94 (0.88, 1.00)
BMI	1.06 (1.03, 1.09)**	1.08 (1.05, 1.11)**	1.05 (1.02, 1.09)**	1.00 (0.94, 1.07)	1.02 (0.99, 1.06)	0.93 (0.84, 1.04)
Smoker (ref: smoker)	0.78 (0.40, 1.53)	0.53 (0.27, 1.02)	1.19 (0.44, 3.22)	1.03 (0.26, 4.05)	2.05 (0.44, 9.55)	0.22 (0.03, 1.55)
Experimental group (ref: control)	1.62 (1.17, 2.24)**	1.46 (1.04, 2.04)*	1.59 (1.07, 2.35)*	1.89 (0.99, 3.59)*	1.48 (0.61, 3.58)	0.52 (0.10, 2.59)

Note: Models are adjusted for practice clustering and potential site difference. Bold indicates significance.

* $p \leq 0.05$; ** $p \leq 0.01$

history could legitimately classify them as having elevated risk for disease. It should be noted, however, that relatively fewer individuals (range: 3%–7%) believed they were at elevated risk when, according to the assessed familial risk, their risk was average. The study was therefore limited in its ability to determine the impact of the tool on lowering elevated risk perceptions, since it could not be reasonably determined whether modifying these perceptions would render them more consistent with actual disease risk. In addition, because the measures of perceived and familial risk were based on different scales (comparative risk versus absolute risk), the determination of what was considered “congruent” simply reflects concordance between low/high categories within each measure, and not any real assessment of accuracy in risk estimation per se.

Finally, although modifying disease risk perceptions may be considered an important intermediate outcome, future studies are needed to determine whether changes in risk perceptions, and other psychosocial indicators, correspond to changes in health behaviors following family history assessment and tailored feedback.¹⁷ It remains to be determined whether changes in risk perceptions correspond to changes in health behaviors in the Family Healthware™ trial. Analyses focused on addressing this question will be reported in a forthcoming paper.

Conclusion

Family Healthware was effective at increasing disease risk perceptions, particularly for metabolic conditions, among those who underestimated their risk. Results from this study also demonstrate the relatively resistant nature of risk perceptions.

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