

# Implementation of health risk assessments with family health history: barriers and benefits

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## ABSTRACT

Health risk assessments provide an opportunity to emphasise health promotion and disease prevention for individuals and populations at large. A key component of health risk assessments is the detailed collection of family health history information. This information is helpful in determining risk both for common chronic conditions and more rare diseases as well. While the concept of health risk assessments has been around since the Framingham Heart Study was launched in the 1950s, and such assessments are commonly performed in the workplace today, the US healthcare system has been slow to embrace them and the emphasis on prevention that they represent. Before wider implementation of health risk assessments within healthcare can be seen, several concerns must be addressed: (1) provider impact, (2) patient impact, (3) validity of patient-entered data and (4) health outcomes effect. Here, we describe recent developments in health risk assessment design that are helping to address these issues.

## INTRODUCTION

In the progression from health to disease, several transitions occur. The first is from healthy to pre-symptomatic, where disease is present, but the individual feels well, and is unaware of the condition. An example of this health state is the beginning of hypertension when an individual's blood pressure is elevated, but they are unaware of it. The second is from presymptomatic to disease diagnosis, and the third is from diagnosis to disease status, which can be either well controlled or uncontrolled. Health risk assessments (HRAs) are an important element of the healthy stage. The purpose of HRAs is to evaluate an individual's risk for developing common chronic diseases (see [table 1](#) for examples), allowing clinicians to develop personalised care plans; tailoring preventive care, screening and testing to each individual's level of risk to extend health while balancing effectiveness and harms of each action with the potential risk. An example would be using an HRA to assess breast cancer risk and guide usage of breast MRI for screening. Guidelines recommend only using breast MRI in women with a certain level of risk. The goal of such efforts is to maximise benefit and minimise harm for each individual and also, when taken as a whole, for the population as well. Unfortunately, a number of constraints limit the use of HRAs in primary care, where they would be most effective. The objectives of this article are to discuss (1) the history of HRA development, (2) what the key components of HRAs are and (3) the barriers and benefits to their implementation with regard to

providers, patients, data integrity and health outcomes.

## Origins of HRA

In 1948, the Framingham Heart Study, an innovative longitudinal study arising from the field of epidemiology, was introduced by the Assistant Surgeon General, Joseph Mountain. The goal, as devised by the director, Thomas Dawber, was to closely follow a group of residents of Framingham, Massachusetts, using data collected to develop a risk prediction model for cardiovascular disease (CVD).<sup>1</sup> Despite initial scepticism within academia and clinical practice, the trial was successful beyond expectations, and the field of HRA was born. In 2009, when the term 'precision medicine' was coined by Clay Christensen, he defined it as precisely predicting a medical outcome by combining a variety of data into risk algorithms.<sup>2</sup> According to this definition, HRAs are simply the application of precision medicine to those who are healthy.

*Framingham Heart Study:* A long-term ongoing cardiovascular research study of the residents of the town of Framingham, Massachusetts, USA. The study began in 1948 with 5209 adult subjects, and is now on its third generation of participants. Through the study, the first HRA was developed.

Most HRAs today include the following elements: data collection (either through a web-based or paper questionnaire), risk assessment and report of risk results. For data collection, data collected depends on which conditions are included in the risk assessment. At a minimum, demographics, lifestyle, personal health history, family health history (FHH) and biometrics (such as blood pressure, weight, cholesterol, etc) are included. Other types of data, such as genetic/genomic data and individual preferences regarding comfort with risk, are just now starting to be incorporated into some models, and have the potential to refine the accuracy of risk calculations and improve shared decision making with medical providers.<sup>3 4</sup> The last component, the risk results report, may or may not provide guidance about how to manage your risk. Some are exceptionally detailed and even indicate how much your risk can be lowered by initiating one or more recommended preventive actions, while others merely indicate that you are at increased risk for the specified condition.

## The value of FHH

FHH, while unassuming and often disregarded, is an essential data element in HRAs. FHH is often



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**Table 1** Examples of conditions for which family health history-based health risk assessment is useful

	Risk algorithm based on family health history only	Risk algorithms include family health history
Hereditary breast and ovarian cancer		x
Hereditary non-polyposis colon cancer (Lynch syndrome)	x	
Alpha-1 antitrypsin deficiency	x	
Diabetes mellitus type 2		x
Abdominal aortic aneurysm		x
Coronary artery disease		x
Haemochromatosis	x	
Maturity-onset diabetes of the young		x
Inflammatory bowel disease		x
Stroke		x
Gastric cancer		x
Renal cancer		x
Age-related macular degeneration		x

the strongest or only predictor of disease risk (see table 1). An example of the impact of FHH on common disease risk is CVD, where having a parent with premature CVD increases an individual's odds of having a heart attack by 2.0.<sup>5</sup> While many other factors contribute to CVD risk, it is well established that patients' identify with FHH and that counselling regarding FHH risk has the ability to change patient behaviour.<sup>6-8</sup>

In some conditions, excluding an FHH can lead to missing those at highest risk for the disease. For example, many risk assessments for chronic kidney disease ask about high blood pressure and race, but do not ask about family history; however, those with autosomal dominant polycystic kidney disease, a hereditary condition that runs in families, are at the highest risk of developing chronic kidney disease even without high blood pressure.<sup>9</sup> Endometrial cancer, a tumour of the uterus, is another example. Almost all risk assessments include exogenous oestrogen, obesity and some include family members with endometrial cancer, but most do not ask about a family history of other cancers even though endometrial cancer is part of the constellation of cancers that can occur in two hereditary cancer syndromes, Lynch syndrome and Cowden syndrome.<sup>10</sup> While those with hereditary cancer syndromes or polycystic kidney disease are only a small proportion of those developing these two conditions, they are the ones at the highest risk of developing disease.

#### Syndrome definitions

**Lynch syndrome:** an inherited condition that increases your risk of colon cancer and other cancers. It has historically been known as hereditary non-polyposis colorectal cancer.

**Cowden syndrome:** a disorder characterised by multiple non-cancerous tumour-like growths called hamartomas and an increased risk of developing certain cancers.

In addition to being highly predictive, risk due to FHH is frequently actionable. Numerous evidence-based guidelines assign the level of disease risk associated with a given combination of affected relatives, and recommend specific actions to mitigate

risk. For example, the National Comprehensive Cancer Network's guidelines for breast and ovarian cancer recommend breast cancer susceptibility gene (BRCA) testing if an individual has even one family member with ovarian cancer.<sup>11</sup> Another example is haemochromatosis. If an individual has a first-degree relative with the condition then baseline iron studies and genetic testing are recommended.<sup>12</sup> Thus, FHH is the only data element that is both highly predictive and actionable in combination with other data elements *and* by itself.

#### The gap in implementation

Despite the success of the Framingham Heart Study, further development and implementation of HRAs gained little traction until an HRA developed by the Center for Disease Control (CDC) was made publicly available in 1980.<sup>13</sup> Incidentally, the 1980s were also a time when rapidly increasing healthcare costs were becoming a problem for employers and insurers. HRAs were seen as a way to manage these costs.<sup>14</sup> Through further collaborative effort by Prudential and the CDC, they demonstrated that HRAs could ultimately lower company healthcare expenditures, as well as reduce absenteeism and increase productivity.<sup>15 16</sup> These findings and Prudential's takeover of the CDC programme in 1986 led to rapid uptake among US employers and insurance companies; however, uptake continued to be anaemic in the healthcare setting.<sup>13</sup>

There are several explanations for why implementation in the healthcare system failed to take root. The current structure of healthcare in the United States has led to a disconnect between public health and healthcare, increasing demands on primary care providers and a perverse incentive system that rewards aggressive disease treatment over the maintenance of health.<sup>13 17</sup> This combination of features encouraged the development of a healthcare system incapable of responding to the needs of the healthy segment of the population due to a vicious cycle dominated by sick patients getting sicker, less time to address prevention among healthy patients and ultimately healthy patients getting sick.<sup>18</sup> Given this environment, it is understandable that uptake of HRAs in clinical practice was slow.

Fortunately, these barriers to prevention have been highlighted in recent studies, and their unsustainable impact on the US healthcare system has been recognised. In particular, the five Mirror, Mirror studies performed by the Commonwealth Fund, which assessed cost and quality of healthcare in 11 international healthcare systems between 2004 and 2014, ranked the USA last in quality and highest in expenditures, and showed that there had been little improvement over the 10-year period.<sup>19</sup> In addition, the Affordable Care Act (ACA) of 2010 has stressed the need for improving quality of care, emphasising prevention and lowering costs. HRAs have been recognised as valuable assets to reaching these objectives and integral tools for redesigning healthcare systems. Through the ACA, Medicare beneficiaries are now provided free annual wellness examinations that include an HRA. That being said, widespread implementation of HRAs in primary care still has many practical impediments that need to be addressed: minimisation of provider burden, ease of use for patients, data quality (particularly FHH data) and clinical effectiveness in primary care populations. Each of these is described in detail below.

#### BARRIERS AND BENEFITS

##### Impact on providers

Providers, primary care providers in particular, routinely face the challenge of balancing health maintenance and disease

prevention issues, which are of longer lasting significance, with concerns that may be of higher acuity, but less long-term import. With face times shrinking to just over 9 min for most appointments, the tyranny of the urgent often wins out.<sup>18</sup> In addition, because the steps involved in HRAs (ie, data collection, risk calculation and evidence synthesis) are complex and time consuming, integration into normal work flow can be challenging.<sup>20</sup> Risk algorithms are often more complex than can be done manually, and the calculators for each condition are typically found in various places across the web, and most are not integrated into electronic medical record systems. In addition, producing an actionable risk management plan is difficult in the face of the magnitude of literature available. Efforts to foster discussion with providers around these topics have not been successful due to many of the same reasons that implementing HRAs has lagged.<sup>21</sup>

The rapidly developing field of health information technology (IT) may offer one solution to these complex and inter-related barriers. Patient-facing web-based or computer-based HRA tools can: transfer the data collection component from the clinical setting to the patient's home, and provide algorithm-based risk calculations and discreet actionable steps as part of the risk management plan for the provider at the point of care. Several such FHH-based HRA tools have been built with these capabilities.<sup>22</sup> Table 2 gives examples of currently available tools and their characteristics.

Uptake of these tools has been anecdotally promising. Currently, there is only one published study that reports physician experience with and uptake of an HRA tool. That study reported that primary care providers felt the HRA tool tested was easy to incorporate into workflow (100%), improved their quality of care (85%), made their practice easier (75%) and enhanced their understanding of the importance of FHH

(62%).<sup>23</sup> These results suggest that with the right combination of features, electronic HRA tools can be accepted and valued by busy primary care clinicians.

### Impact on patients

If patient-facing tools were taken up by primary care providers, some have raised concern that patients do not have the IT know-how to use these tools or the inclination to do so. Current trends in patient usage of the internet to inform health do not support this view. Millions of patients use the internet on a daily basis to better understand their health.<sup>24 25</sup> Even among minorities and those with household incomes of \$25 000–\$50 000 per year, internet use is over 66%.<sup>26</sup> In addition, individuals recognise the value of FHH with over 90% of Americans surveyed reporting that their personal health is impacted by their FHH.<sup>27 28</sup> When health systems place HRAs on their patient portals, significant uptake occurs. For example, the Northshore University Health System launched Health Heritage on their health portal in May 2014, and 500 patients completed the assessment within the first 30 days (unpublished data, Lori Orlando, 2015). This was without any organised plan by the health system to notify patients to the availability of the tool.

There are also concerns of racial and socioeconomic discrimination as those of lower socioeconomic status may not have the IT mastery or access required to complete such tools. In fact, HRA tools can potentially reduce health disparities. Algorithm-based risk assessment is not susceptible to the subconscious biases that providers may bring to the patient encounter. In implementation studies of HRA tools, these disparities have also not borne out with no difference in uptake based on education level or race, two significant risk factors for health-care disparity.<sup>23 29</sup> Patients using one HRA tool, MeTree, reported that the tool was easy to use (94%) and understand

**Table 2** Examples of patient-facing electronic family health history-based health risk assessment tools

Programme	Decision support diseases	Completed by	Publicly available	Who receives output	Available at point of care	Action-oriented recommendation
MeTree	Colon, breast and ovarian cancer; aortic aneurysm, heart disease, stroke, diabetes, hereditary cancer syndrome, hereditary cardiovascular syndrome, hereditary liver diseases	Patient online	In future	Patient and physician	Yes	Yes
Schroy <i>et al</i> GRACE	Colon cancer	Physician	Unknown	Physician	Yes	No
	Breast cancer	Patient in physician's office	Unknown	Patient, clinical nurse specialist, physician	Yes	No
Family Healthware	Coronary heart disease, diabetes, stroke, colon, breast and ovarian cancer	Patient online	No	Patient	No	No
Family HealthLink	Coronary heart disease, cancer	Patient online	Yes	Patient	No	No
CRIS	Colon cancer	Patient in physician's office	No	Patient and physician	Yes	No
MyGenerations	Cancer	Patient online	Yes	Patient	No	No
Hughes RiskApps	Breast and ovarian cancer, colon cancer, hereditary cancer risk	Patient—clinician can revise online or physician's office	Yes	Patient and physician	Yes	No
HealthHeritage.net	87 diseases: multiple cancers, diabetes, neuromuscular diseases and cardiovascular diseases	Patient online	In future	Patient	No	No
Invitae	Cardiac disease, colon cancer, Charcot-Marie-Tooth, breast cancer, pancreatic cancer	Physician online	Yes	Patient and physician	?	No
MyFamily	Cancer, cardiology, gastrointestinal proprietary algorithms	Patient	In future	Physician	Yes	Yes
Myriad	29 cancers	Patient	Yes	Patient	No	No
Power Lineage	Cancer	Patient and physician	Yes	Physician	No	No

(97%) irrespective of education level or race.<sup>23</sup> For what barriers do exist regarding access to such tools, much work is beginning to be done in the use of mobile technologies to address these issues.<sup>30 31</sup>

When patient-facing HRA IT tools are used, patient reactions are overwhelmingly positive. Participants in three studies of HRA tools reported being generally satisfied with their experience (83%–90%), that completing the tool did not cause persistent anxiety (96%) and that they would recommend it to others (93%–99%).<sup>23 29 32</sup> In addition to use of the tool itself being a positive experience, there are additional benefits to the patient of: increased understanding about their risk for disease and the ways to mitigate their risk and more nuanced engagement in their health with the potential for enhanced shared decision making between patients and providers.<sup>3 4</sup>

### Validity of patient-entered data

Concerns have been raised about the reliability of patient-entered data outside the setting of the clinical encounter. In particular, there are concerns about the accuracy of the FHH collected. Questions arise around differentiation of a primary cancer versus metastatic cancer, different types of CVD such as coronary artery disease versus valvular conditions and diseases with names that sound similar such as inflammatory bowel disease and irritable bowel disease. In a systematic review of family history questionnaires, strong agreement (70%–100%) was found between patient-entered data and the presumed gold standard of genetic counsellor-acquired data.<sup>33</sup> In comparison with what is typically collected in routine practice, patient-entered data are significantly superior.<sup>20 29 33 34</sup> In the evaluation of MeTree, less than 4% of patients' medical records prior to the HRA implementation contained high-quality family history information documented for even one relative.<sup>35</sup> With the use of MeTree, >99% of family history data entered by patients had at least one relative with high-quality family history information, and over 50% of pedigrees had at least 50% of relatives with high-quality information.<sup>36</sup>

When patients are offered education and the opportunity to discuss their FHH with relatives, even further improvements in accuracy and comprehensiveness can be seen.<sup>37</sup> Understanding the essential elements of a quality FHH and using that information to guide discussions with family members results in almost half of patients providing new or updated information and a change in recommendations for disease risk management for 16% of patients.<sup>38</sup>

### Do HRA tools improve clinical care?

Patient and provider barriers addressed, impact on outcomes must still be shown. A considerable number of guidelines tailor recommended risk management strategies to an individual's risk for disease, and HRAs offer the ability to bring the guidelines for various conditions together into one succinct, but comprehensive, report. Screening strategies recommended for higher risk individuals have a greater sensitivity than population-based screening approaches, but are also typically associated with higher costs or greater potential adverse events that warrant limiting them to those at the highest level of disease risk. This approach of tailored risk management helps to balance benefits and harms for the individual patient and when assessed at the population level helps identify those at higher risk and minimise overuse among those at average risk. To show that HRAs are, in fact, able to increase uptake of these guidelines and improve individual/population health, they need to be able to: improve identification of individuals at increased disease risk, increase

the match between risk level and risk-management strategy and improve patient acceptance of management recommendations above what is currently occurring in routine care.

Surveys of providers have shown that physicians do not feel confident in their comprehension of the guidelines regarding risk, and frequently overestimate or underestimate the risk.<sup>39–42</sup> Fortunately, several studies have shown that FHH-based HRAs can accurately estimate risk, and identify a significant number of patients who were not identified during routine visits with their providers.<sup>34 43</sup> For example, the Family Healthware trial found that 82% of participants were at strong or moderate risk for at least one of six conditions;<sup>44</sup> the Health Heritage trial found 42% to be at increased risk<sup>29</sup> and the MeTree study found 44% to be at increased risk.<sup>45</sup>

While numerous studies have shown that HRAs can improve discrimination between average-risk and high-risk individuals, less has been published regarding the impact on behaviour of providers and patients as a result of this risk information. Results regarding the HRA tool, MeTree, showed decreased overuse of high-risk services among average-risk individuals by 81% while increasing use among appropriate high-risk individuals (unpublished data, Lori Orlando, 2015). In another study, a significant increase in referrals to genetic services was seen with the implementation of a breast cancer risk assessment tool, Hughes RiskApps.<sup>46</sup> Quereshi *et al*<sup>43</sup> showed significant improvements in smoking cessation rates with use of a FHH-focused HRA. These findings, showing the value of FHH usage, have been borne out through other studies as well.<sup>6 47</sup> Trials are ongoing to better understand how to engage patients and providers in shared decision making surrounding patients' behavioural and psychosocial risks.<sup>4</sup> Further work needs to be done in this area to better understand the impact of HRAs on patient and provider behaviour as it relates to screening.<sup>48</sup>

### CONCLUSION

HRAs, a precision medicine tool intended to be used by healthy patients, hold promise for the enhancement of preventive care by improving both individual health and population health through accurate estimation of risk for disease and improvement of the match between risk level and risk-management strategy. HRA tools may also enhance patient experiences by increasing patient activation and shared decision making, thereby incorporating patient values into the patient–provider encounter and improving adherence to recommendations. HRAs' accuracy in assigning risk can be further improved as more structured FHH data are collected and analysed to understand the true risk conveyed by familial illness. Just as the National Institutes of Health is encouraging data sharing among randomised controlled trials, similar efforts are needed between large structured FHH databases so that guidelines can be further refined to reflect the true risk associated with a family history of various conditions.

Furthermore, enhancement of such tools' accuracy and effectiveness may be achieved by combining genetic and genomic data about disease risk into current risk algorithms. While uptake of patient-facing HRAs has been slow to start in the US healthcare system, they are beginning to gain traction as the evidence base builds and innovations in health IT allow improved incorporation into clinical workflow. HRA is one of the few precision medicine tools that is ready for immediate translation into clinical care (especially primary care) and as such can pave the way for translation of other genomic and personalised medicine advances in these fields by increasing clinicians' familiarity with these types of tools and their benefits.

Main messages

- ▶ Family health history (FHH) is an essential element of health risk assessment (HRA).
- ▶ HRAs document FHH better than is done in routine practice.
- ▶ HRAs identify a significant number of patients who have above-average risk for specific conditions.

Current research questions

- ▶ What is the role of health risk assessments in the continuum of care?
- ▶ What are the potential barriers to implementation of health risk assessment tools?
- ▶ How does implementation of health risk assessment tools impact population health?

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Self assessment questions

Please answer true or false for the below statements:

1. Health risk assessments (HRAs) benefit patients during the symptomatic stage of disease.
2. The Framingham Heart Study developed the first risk prediction model in the USA
3. HRAs were first and most successfully taken up by employers and insurance companies.
4. All HRAs provide clinical decision support.
5. HRAs can have impact at a population level.

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### Answers

1. False
2. True
3. True
4. False
5. True