HeartAware 3.0 Client Review Document

Overview

The HeartAware HRA calculates a user's 10-year (near-term) and 30-year (long-term) risk of developing cardiovascular disease, as well as "Heart Age."

Main Scientific Basis

Risk estimates in this HRA are based on the Framingham Heart Study.[1,2]

Product Description

The HeartAware HRA asks a series of questions. Using algorithms from the Framingham Heart Study,[1,2] it calculates a 10-year and 30-year risk of cardiovascular disease (CVD). Users of this HRA also learn their Heart Age. Heart Age is the age at which an individual with no risk factors matches the estimated risk percentage of the individual taking the HRA. The calculated Heart Age may be older, younger, or equal to the user's actual age. It is a good way to communicate what the long- and near-term risk categories mean.

The HRA also gathers valuable information about existing cardiovascular disease and diabetes status and specifically reports on the major cardiovascular disease risk factors.

Key Results Provided

The Framingham 10-year risk, 30-year risk and Heart Age are calculated, and the most concerning result is then shown to the user as their primary result. The 10-year risk is weighted the most in the primary result algorithm. The results are categorized into high, moderate, low, unknown, high with existing cardiovascular disease, and increased due to heart age. Follow-up messaging, emails, and programs can be developed to align with these categories.

About the 10-Year Risk Calculation

The 10-year cardiovascular disease (CVD) risk is based on the Framingham Heart Study and the follow-up Framingham Offspring Study. The calculation is described in a report published by D'Agostino, et al in 2008.[1] This article contains sex-specific multivariable risk factor algorithms to calculate the 10-year risk of general CVD. The calculations estimate the 10-year risk of full CVD, which includes previous CVD, coronary insufficiency, angina pectoris, transient ischemic attack, intermittent claudication, or congestive heart failure. The article reporting the Study contains two paths for risk estimation. The HeartAware HRA utilizes the BMI-based estimation.

The 10-year risk of CVD calculation is overridden and set to "20% or more" if the user has any of the following existing conditions:

- Coronary heart disease

- Other cardiovascular disease:
  - Heart disease
  - Heart attack

- Stroke or transient ischemic attack (TIA)
- Heart failure
- Angina or chest pain
- Peripheral artery disease (PAD)

- Diabetes
  - Diabetes counts as a CHD risk equivalent because it confers a high risk of new CHD within 10 years, in part because of its frequent association with multiple risk factors. Furthermore, because persons with diabetes who experience a myocardial infarction have an unusually high death rate either immediately or in the long term, a more intensive prevention strategy is warranted. (ATP III, Executive Summary) [3]
  - Diabetes is categorized into three types (no diabetes, prediabetes, or diabetes) based on the current version of the Practice Guidelines from the American Diabetes Association.[4]

CVD Risk Categories

The HeartAware HRA assigns a category of High Risk, Moderate Risk, or Low Risk based on the risk percentage from Framingham. Additionally, the risk category of Moderate is assigned if the 10-year risk percentage is less than 10% and the user has two or more of the following risk factors: [3]

- Tobacco use
- Hypertension (BP $\geq$140/90 mm Hg or on antihypertensive medication)
- Family history of premature CHD (CHD in male first degree relative <55 years of age; CHD in female first degree relative <65 years of age)
- Age (men $\geq$45 years, women $\geq$55 years).

About the 30-Year Risk Calculation

The 30-year risk calculation is also based on the Framingham Heart Study as reported by Pencina et al, 2009.[2] The algorithm calculates the users' 30-year risk using age, sex, systolic blood pressure, smoking status, diabetes status, and BMI. The calculations estimate the 30-year risk of full CVD, which includes previous CVD, coronary insufficiency, angina pectoris, transient ischemic attack, intermittent claudication, or congestive heart failure. This is the same outcome as calculated for 10-year CVD Risk in: D'Agostino et al, 2008.[1]

CVD Risk Factors

The HeartAware HRA evaluates the users' inputs and assigns a rating of High Risk, Moderate Risk, or Low Risk to each CVD risk factor. Several modifiable risk factors are categorized based on the widely accepted guidelines of the American Heart Association's strategic Impact Goal through 2020[5] published in February 2010 and The MORGEN Study of sleep impact on CVD incidence published in 2011[7]. The risk factors are:

- Tobacco use
- Weight
- Blood pressure

- Cholesterol
- Physical Activity
- Sleep duration and quality

2017 Hypertension Guideline Update from AHA/ACC

The HeartAware HRA uses the global cardiovascular disease risk assessment algorithms from the Framingham Heart Study and the follow-up Framingham Offspring Study published in 2008 and 2009. One of the risk factors is systolic blood pressure. The Framingham cut-points and corresponding categories within the HeartAware HRA align with the 2017 AHA/ACC Guidelines[6] with exception of the 130-139 range, defined in the 2017 guidelines as "high-stage 1." The clinical nomenclature of "stage 1" and "stage 2" was avoided in the HeartAware HRA. Instead, the terms "moderately high" and "high" were deemed more user-friendly and sufficiently descriptive names for those categories.

References

1. D'Agostino R, Vasan RS, Pencina MJ, et al. General cardiovascular risk profile for use in primary care, the Framingham heart study. *Circulation*. 2008;743-753.

2. Pencina MJ, D'Agostino RB, Sr., Larson MG, et al. Predicting the 30-Year Risk of Cardiovascular Disease. The Framingham Heart Study. *Circulation*. 2009.

3. National Cholesterol Education Program Expert Panel on Detection Evaluation and Treatment of High Blood Cholesterol in Adults Adult Treatment Panel III. *Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Executive Summary.* National Cholesterol Education Program. National Institutes of Health: National Heart, Lung, and Blood Institute; May, 2001.

4. American Diabetes Association. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2019. *Diabetes Care* 2019;42(Supplement 1): S13-S28. DOI: https://doi.org/10.2337/dc19-S002.

5. Lloyd-Jones DM, Hong Y, Labarthe D, et al. Defining and setting national goals for cardiovascular health promotion and disease reduction: the American Heart Association's strategic Impact Goal through 2020 and beyond. *Circulation*. 2010;121:586-613.

6. Whelton PK, Carey RM, et al. AHA/ACC guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. *Hypertension*. 2017;00:e000-e000.

7. Hoevenaar-Blom MP, Spijkerman AMW, et al. Sleep duration and sleep quality in relation to 12-Year cardiovascular disease incidence: the MORGEN Study. *SLEEP* 2011;34(11):1487-1492. DOI: http://dx.doi.org/10.5665/sleep.1382.