

The Framingham Heart Study and Risk Assessment

Introduction

The Framingham Risk Assessment Program is a diagnostic tool that is one of the many features of the Cholestech LDX® System. This program calculates the percent risk of developing coronary heart disease (CHD) over a selected period of time based on lipid test results and several risk factors. The Cholestech LDX CHD Risk Assessment Program is based on data from the Framingham Heart Study.

History of the Framingham Heart Study

Framingham is a small city in Massachusetts, west of Boston, where a group of physicians from the National Heart, Lung & Blood Institute (NHLBI) started an epidemiology study in September 1948. An epidemiology study is one where researchers observe but do not intervene with medication as in a clinical study. In the beginning of the study, 5,209 male and female volunteers between the ages of 30 and 60 joined and in 1971, 5,123 of their offspring joined the study as well. The researchers saw the first group every two years and the second group every four years, taking blood pressure, heart rate and performing 84 medical tests on each volunteer. The subjects were then asked a very thorough set of questions regarding eating and sleeping habits, including smoking and drinking, along with questions about their mental health.

Researchers gathered data and began publishing their findings approximately 10 years after the start of the study in 1948 and have continued to the present. They coined the term 'risk factor' and identified several risk factors over the years. Smoking, high blood pressure, obesity, loss of estrogen and diabetes have been

shown to increase the risk of heart disease, while physical activity and high levels of high-density lipoprotein (HDL) cholesterol can reduce the risk. The information that has been collected and released for public knowledge has had a profound influence on diagnosing and treating CHD. The death rate from heart disease has steadily dropped since 1963. The researchers are continually identifying new risk factors. For example, in 1987 researchers identified that high levels of homocysteine, an amino acid, can be a contributing factor to the build up of fatty substances in the arteries. They have also been gathering data and looking at the genetic aspect of CHD. In addition, the original participants were mostly Caucasians of European descent, but researchers have been adding minorities to the study since 1995. The study has also provided information for the study of cancer, osteoporosis, and arthritis.

Third Generation Study

In 2001 the Framingham Heart Study announced that the study was to enter a new phase by recruiting its third generation of participants. About 3,500 grandchildren of the original participants will be recruited for the third phase of the study. The goals of the Third Generation Study are to:

- Identify new risk factors for cardiovascular, lung and blood diseases.
- Identify the genetic factors that contribute to both good health and cardiovascular disease.
- Develop new tests that can detect the early stages of coronary atherosclerosis in otherwise healthy adults.

It is important to understand the limitations of the Framingham risk estimate. The Framingham cohort was a relatively small, homogeneous population of white Americans from a single town. Framingham residents may not represent the characteristics of other ethnic, social, or geographic groups. NHLBI investigators recently tested the Framingham risk equations in 6 ethnically diverse study cohorts.² They found that the equations performed reasonably well in white and black American men and women. But the equations systematically overestimated risk among Japanese-American and Hispanic men and Native-American women. NHLBI investigators and others are currently working on methods to adjust the risk assessment to accommodate these differences.

How To Use The Risk Assessment on the Cholestech LDX

In order to use this feature on the LDX, you must turn it 'on' in the Configuration Menu.

1. To enter the Configuration Menu, press the STOP button and hold down until the Firmware Version appears.
2. The first item in the Configuration Menu will then be displayed: "Lang=English".
3. Press the RUN button to move through the items (5 times) until you get to "Risk-off".
4. Press the DATA button briskly to turn the Risk choice to "Framingham".
5. Press STOP to exit the Configuration Menu.

To turn the Framingham Risk Assessment 'off' follow the directions above and when you get to "Risk=Framingham," press the DATA button to turn the Risk choice to "off", then press STOP to exit the Configuration Menu.

The Framingham Risk Assessment can be run on any patient results that include a total cholesterol and HDL.

1. After a test cassette is run, press the DATA button once to view the calculated results. Press the DATA button again to enter the Risk Assessment Program. The screen will display "Risk? RUN=yes, STOP=no".

2. Press the RUN button to enter the Risk Assessment.

3. Press the DATA button to enter patient information, then press the RUN button to enter your selection and go to the next menu item. You will be asked to enter:

- a. Sex (male or female)
- b. Smoke (yes or no)
- c. Diabetes (yes or no)
- d. ECG-LVH, Left Ventricular Hypertrophy measured by an Electrocardiogram (yes or no)*
- e. Age (30 - 74 years)
- f. SBP, Systolic Blood Pressure (90-200 mm Hg, in increments of 5).
- g. Year, number of years into the future for the risk projection (4-12 years).

4. After all the information is entered, "Print? RUN=yes, STOP=no" will appear on the display. Press RUN to print the results. You will see the risk percentage appear on the display while the results print.

* Left Ventricular Hypertrophy is the enlargement of the left pumping chamber of the heart. The most common cause of this thickening of the chamber wall is due to high blood pressure over a substantial period of time. An electrocardiogram diagnoses this condition.

Interpreting the Results

Male

Age (years)	Average 10 Yr CHD Risk	Low* 10 Yr CHD Risk
30-34	3%	2%
35-39	5%	3%
40-44	7%	4%
45-49	11%	4%
50-54	14%	6%
55-59	16%	7%
60-64	21%	9%
65-69	25%	11%
70-74	30%	14%

Female

Age (years)	Average 10 Yr CHD Risk	Low* 10 Yr CHD Risk
30-34	<1%	<1%
35-39	<1%	1%
40-44	2%	2%
45-49	5%	3%
50-54	8%	5%
55-59	12%	7%
60-64	12%	8%
65-69	13%	8%
70-74	14%	8%

* Low risk was calculated for a person the same age, with optimal blood pressure, LDL 100-129 mg/dL or cholesterol 160-169 mg/dL, HDL 45 mg/dL for men or 55 mg/dL for women, non-smoker, and no diabetes.⁵

Risk Assessment Modeling

A good way to use the Framingham Risk Assessment as a diagnostic tool is by doing risk assessment modeling. After running a test and performing an initial risk assessment, the Cholestech LDX Framingham Risk Assessment Program allows you to change the information in the file to see how these changes will impact the patient's risk of developing heart disease. This helps to illustrate the effect that lifestyle changes can have. Only manually entered items can be modified.

To run another risk assessment on the same patient results:

1. Recall the patient's test results by pressing DATA. Do not press RUN; this will delete the stored results. Press DATA a second time for calculated results.

2. Press the DATA button a third time to reenter the Framingham Risk Assessment Program. The screen will display "Risk? RUN=yes, STOP=no".

3. Press the RUN button to advance to the risk factor you wish to modify.

Follow the same instructions for performing a CHD risk assessment.

4. When finished, the new percent risk of developing CHD (providing the patient makes the identified changes) will be displayed.

5. To exit the Framingham Risk Assessment Program press STOP.

As an example, here are the Framingham Risk Assessment results for a 55 year old man with moderately high cholesterol:

TC	231 mg/dL
HDL	38 mg/dL
TRG	150 mg/dL
LDL	163 mg/dL
TC/HDL	6.1
Sex:	Male
Smoke:	YES
Diabetes:	NO
ECG-LVH:	NO
Age:	55
Systolic BP:	125
Year:	10
Risk:	21%

If we change one risk factor, Smoke, to 'NO', and keep all other factors the same, his new 10 year risk is decreased to **14%**.

Calculation of the Framingham Risk

The risk calculation in the Cholestech LDX software is based on the original Framingham Heart Study data. In May, 2001, The ATP III (Adult Treatment Panel) released its report with an updated risk calculation.⁴ In fact, there are two new methods for calculating the risk both based on the Framingham Heart Study data. There is a small difference between the risk estimate calculated by the Cholestech LDX and the two new estimates calculated by the ATP III score sheets. However, these differences are not clinically significant. Cholestech plans to update the risk calculation to the most current algorithm with the next major revision of the ROM software.

Summary

The Framingham Risk Assessment feature on the Cholestech LDX is an easy, powerful tool that gives patients a look at their future risk of developing CHD. It provides them with important information that they can use to make lifestyle changes that can reduce their risk of coronary heart disease.

References

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4. Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). *JAMA* 2001; 285:2486-97.
5. Wilson PW, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of coronary heart disease using risk factor categories. *Circulation* 1998; 97:1837-1847.

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