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CHOLESTECH LDX™

CHD Risk Assessment

INTRODUCTION

The goal of treating high cholesterol is to prevent coronary heart disease (CHD). According to the clinical practice guidelines of the National Cholesterol Education Program (NCEP), it is necessary to assess an individual's risk for CHD in order to determine whether and how aggressively to treat. The Adult Treatment Panel III (ATP III) guidelines employ a 10-year CHD risk assessment approach based upon the findings of the Framingham Heart Study.[1] The Cholestech LDX System includes a program enabling the calculation of CHD risk according to the NCEP ATP III guidelines.

THE FRAMINGHAM HEART STUDY

Framingham is a town in Massachusetts, west of Boston, where a group of clinical researchers from the National Heart, Lung & Blood Institute (NHLBI) started the Framingham Heart Study, a groundbreaking epidemiology study in September 1948. An epidemiology study is one where researchers observe but do not intervene with medication as in a clinical trial. The original study population (cohort) consisted of two-thirds of the adult population of the town, 5,209 male and female volunteers between the ages of 30 and 60 years. In 1971, 5,123 of their offspring joined the study as well. The Framingham Heart Study continues to the present day with the addition of more cohorts, including the grandchildren of the original cohort.[2]

Study participants are seen frequently by researchers, who measure a battery of medical tests, including blood pressure, and laboratory tests such as lipids, glucose, and many others, and inquire about medical history and a host of lifestyle factors. Surviving members of the original cohort completed their 30th study visit between 2008 and 2010.

Framingham study researchers have published over 2000 papers summarizing their findings since the start of the study. They coined the term 'risk factor' and have identified many risk factors over the years. Age, smoking, high cholesterol, low levels of HDL cholesterol, high blood pressure, family history of CHD, and diabetes are all powerful predictors of CHD risk. Lifestyle factors such as stress, obesity, and physical inactivity are also important. Having high levels of HDL cholesterol confers a protective effect.

Framingham Heart Study researchers have developed a variety of approaches for assessing CHD or cardiovascular disease risk over the years. These methods incorporate the major risk factors into complex algorithms or more simplified scoring schemes.[3,4] These Framingham risk scores have looked at a variety of different outcomes, such as the "hard" endpoints of myocardial infarction and CHD death, or broader ones that extend to stroke, heart failure, and peripheral vascular disease. The time horizon of the risk score has also varied from a few years to a lifetime.[3-5] And the researchers have also examined ways to make the risk scores more accurate in populations from different ethnic backgrounds than the fairly homogeneous population in Framingham, Massachusetts.[6]

CHD RISK AND ATP III

In the NCEP ATP III guidelines, the risk factors of diabetes and family history are addressed before CHD risk assessment using Framingham scoring is conducted.[1] CHD risk assessment, employing age, gender, smoking, blood pressure, and total & HDL cholesterol is performed using either a complex algorithm or a simple scoring scheme. Results may be slightly different for individuals by these two approaches, but the difference will not be clinically significant. CHD risk results are expressed as a percentage of risk over the next 10 years.

CHD RISK ASSESSMENT USING THE CHOLESTECH LDX ANALYZER

The CHD Risk assessment feature of the Cholestech LDX System uses the NCEP ATP III scoring tables (see last page of this System Brief).[1] The following instructions are for ROM v3.40 and later. In order to use the CHD Risk feature 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 until you get to "Risk-Off".

4. Press the DATA button briskly to turn the Risk choice to "Risk=CHD Risk".

5. Press STOP to exit the Configuration Menu.

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

The CHD Risk Assessment can be run on any patient results generated with an Cholestech LDX test cassette that includes total cholesterol (TC) and HDL cholesterol (HDL).

1. After a test cassette is run, press the DATA button as many times as needed for the cassette type you are using until you have seen all of the calculated results. Press the DATA button again to enter the CHD Risk Assessment Program. The screen will display "Risk? RUN=yes, STOP=no".

2. Press the RUN button to enter the CHD 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. Age (20–79 years in 5-year increments)

   b. Sex (male or female)

   c. Smoke (yes or no)

   d. SBP, Systolic Blood Pressure (<120 to ≥160 mmHg in increments of 10 mmHg)

   e. BP treated (yes or no)

4. After all the information is entered, "10 year CHD risk =" will be displayed with the calculated CHD risk percentage.

5. Press DATA or RUN: "Print? RUN=yes, STOP=no" will appear on the display. Press RUN to print the results.

RISK ASSESSMENT MODELING

While not advocated by the NCEP, many clinicians use CHD Risk Assessment as a counseling tool by doing risk assessment modeling. After running a test and performing an initial risk assessment, the Cholestech LDX Risk Assessment Program allows you to change the information in the file to see how these changes will impact the individual's risk of developing CHD. 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 individual's test results by pressing DATA. Do not load a new cassette and 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 CHD 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 individual makes the identified changes) will be displayed.

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

As an example, here are the CHD Risk Assessment results for a 55-year-old man with moderately high cholesterol and who is not treated for high blood pressure:

```
**Cholestech LDX v3.40**
22 Jun 2018 11:10 A.M.
SAMPLE= Whole B.
_____
Name/ID
TC=231          mg/dL
HDL=38          mg/dL
TRG=150         mg/dL
LDL=163         mg/dL
non-HDL=193     mg/dL
TC/HDL=6.1

Sex= M        Smoke=YES
BP Treated=NO
Age=55-59 SBP=<125
10-Year CHD Risk=25%
```

If we change just one risk factor, Smoke, to 'NO', and keep all other factors the same, his new 10 year risk is decreased to 12%.

ESTIMATE OF 10-YEAR RISK FOR MEN

FRAMINGHAM POINT SCORES

AGE	20–34	35–39	40–44	45–49	50–54	55–59	60–64	65–69	70–74	75–79
POINTS	-9	-4	0	3	6	8	10	11	12	13

POINTS

TOTAL CHOLESTEROL	AGE 20–39	AGE 40–49	AGE 50–59	AGE 60–69	AGE 70–79
<160	0	0	0	0	0
160–199	4	3	2	1	0
200–239	7	5	3	1	0
240–279	9	6	4	2	1
≥280	11	8	5	3	1
SMOKER OR NON–SMOKER	AGE 20–39	AGE 40–49	AGE 50–59	AGE 60–69	AGE 70–79
NON–SMOKER	0	0	0	0	0
SMOKER	8	5	3	1	1

SYSTOLIC BP (mmHg)	<120	120–129	130–139	140–159	≥160
IF UNTREATED	0	0	1	1	2
IF TREATED	0	1	2	2	3

HDL (mg/dL)	≥60	50–59	40–49	<40
	-1	0	1	2

POINT TOTAL	<0	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	≥17
10-YEAR RISK %	< 1	1	1	1	1	1	2	2	3	4	5	6	8	10	12	16	20	25	≥30

10-YEAR RISK _____ %

ESTIMATE OF 10-YEAR RISK FOR WOMEN

FRAMINGHAM POINT SCORES

AGE	20-34	35-39	40-44	45-49	50-54	55-59	60-64	65-69	70-74	75-79
POINTS	-7	-3	0	3	6	8	10	12	14	16

POINTS

TOTAL CHOLESTEROL	AGE 20–39	AGE 40–49	AGE 50–59	AGE 60–69	AGE 70–79
<160	0	0	0	0	0
160–199	4	3	2	1	1
200–239	8	6	4	2	1
240–279	11	8	5	3	2
≥280	13	10	7	4	2
SMOKER OR NON–SMOKER	AGE 20–39	AGE 40–49	AGE 50–59	AGE 60–69	AGE 70–79
NON–SMOKER	0	0	0	0	0
SMOKER	9	7	4	2	1

SYSTOLIC BP (mmHg)	<120	120–129	130–139	140–159	≥160
IF UNTREATED	0	1	2	3	4
IF TREATED	0	3	4	5	6

HDL (mg/dL)	≥60	50–59	40–49	<40
	-1	0	1	2

POINT TOTAL	< 9	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	≥25
10-YEAR RISK %	< 1	1	1	1	1	2	2	3	4	5	6	8	11	14	17	22	27	≥30

10-YEAR RISK _____ %

SUMMARY

The CHD Risk Assessment feature on the Cholestech LDX System 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 CHD.

1. 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.
2. www.framinghamheartstudy.org
3. Levy D, Wilson PW, Anderson KM, Castelli WP. Stratifying the patient at risk from coronary disease: new insights from the Framingham Heart Study. Am Heart J 1990; 119:712-716.
4. Wilson PW, D'Agostino RB, Levy D *et al*. Prediction of coronary heart disease using risk factor categories. Circulation 1998; 97:1837-1847.
5. Lloyd-Jones DM, Leip EP, Larson MG et al. Prediction of lifetime risk for cardiovascular disease by risk factor burden at 50 years of age. Circulation 2006; 113:791-798.
6. D'Agostino RB, Sr, Grundy S, Sullivan LM et al Validation of the Framingham coronary heart disease prediction scores: results of a multiple ethnic groups investigation. JAMA 2001; 286:180-7.

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