Framingham Heart Study Risk Calculators Tutorial: History and Usefulness of the Framingham Calculators & SETMA's Innovative Use of Calculators including SETMA's "What If Scenario"

History of Framingham

In 1948, the Framingham Heart Study embarked on an ambitious project in health research to identify the common factors that contribute to cardiovascular disease by following its development over a long period of time in a large group of participants.

The Framingham Heart Disease Epidemiology Study was launched to help physicians better understand heart disease. To do this, researchers examined the lives and habits of ordinary people living in a suburban Boston town called Framingham to determine whether there was any connection between the way they lived and the health of their hearts. They investigated the risk factors that people were born with (*genetic factors*) and those they were exposed to (*environmental factors*), to see which contributed to the development of heart disease.

The researchers recruited 5,209 men and women between the ages of 30 and 62 from the town of Framingham, Massachusetts, and began the first round of extensive physical examinations and lifestyle interviews that they would later analyze for common patterns related to CVD development. Since 1948, the subjects have continued to return to the study every two years for a detailed medical history, physical examination, and laboratory tests, and in 1971, the Study enrolled a second generation - 5,124 of the original participants' adult children and their spouses- to participate in similar examinations.

In 1994, the need to establish a new study reflecting a more diverse community of Framingham was recognized, and the first Omni cohort of the Framingham Heart Study was enrolled. In April, 2002 the Study entered a new phase, the enrollment of a third generation of participants, the grandchildren of the Original Cohort. In 2003, a second group of Omni participants was enrolled.

SETMA's Innovative Use of the Framingham Risk

This tutorial explains the changes and use of SETMA's deployment of the 12 risk calculators published by the Framingham Heart Study. These tools are not absolute and must be used as

an indication of potential cardiovascular and cerebrovascular risk and not as an absolute indicator of future disease. After the tutorial there is detailed information about risk factors and the Framingham.

One of the most interesting tools is the calculation of a patient's relative heart age. It is explained below. This will be a useful tool for encouraging life-style modifications by patients but is only an indication and not an absolute assessment of heart age. If you couple SETMA's "What If Scenario" with the Framingham and SETMA's electronic deployment of the Transtheoretical Assessment of Stages of Change, you can have an effective means of helping patients change their behavior in a sustainable way.

The most innovative use of the Framingham Risk Calculators were suggested by SETMA's associates at the Joslin Diabetes Center in Boston (SETMA is the only multi-specialty Affiliate of the Joslin Diabetes Center).. Drs. Richard Jackson and Ken Snow, while visiting SETMA, recommended the adding of a "What If Scenario" to our display of all twelve calculators.

If You Make a Change it Will Make a Difference

The concept is that we are asking patients to make changes which will not show up as benefits for decades. Of course, ignoring those changes will result in irrevocable deterioration in the patient's health over those decades. But how do you prove to a patient that if you make a change, it will make a difference? One way is with the Framingham Risk Calculators being presented to the patient with the inclusion of the changes which would result if the patient improved the elements of the risk calculator.

Even though these risk calculators are not perfect, they are still the best we have. And, it is imperative that patients know and that their provider knows what their risk is, because it is with the knowledge of the patient's cardiovascular risk that a plan of care and a treatment plan can be designed to help preserve the patient's health.

Remember, Risk is an attempt to determine what the future might be like which means it is imprecise. Some people with a high risk will not experience poor health and some who have low risk will. Overall, however, those with high risk will have more heart attacks and strokes than those with low risk.

Dynamic Complexity

The problem with biological systems is that change, even change which results in deterioration of your health, does not occur quickly and it often occurs without any signs or symptoms until the illness, or disease process has already caused significant damage. There is no explanation of this principle more apt to our use of risk calculators than Peter Senge's explanation of dynamic complexity in *The Fifth Discipline*.

Senge defines dynamic complexity as a situation where cause and effect are subtle, and where the effects over time of interventions are not obvious. This perfectly describes the development of many disease states and the benefit of their treatment. We know that obesity causes, or contributes to most diseases including diabetes, hypertension, heart disease, cancer, etc. In these conditions, -obesity is the cause; cancer is the effect, but the change is slow and is not apparent. Also, the results of treatment are very slow. Consequently, it is hard to sustain the changes necessary to eliminate the cause, which is obesity, in order to avoid the -effect which is cancer.

Shifting the Burden

There are structural problems which aggravate the obvious solutions to a business or a health problem; Senge addresses one of these and calls it the shifting the burden. He defines shifting the burden, as -an underlying problem generates symptoms that demand attention. But the underlying problem is difficult for people to address, either because it is obscure or costly to confront. So people shift the burden of their problem to other solutions well intentioned, easy fixes which seem extremely efficient. Unfortunately, the easier _solutions' only ameliorate the symptoms; they leave the underlying problem unaltered. The underlying problem grows worse, unnoticed because the symptoms apparently clear up, and the system loses whatever ability it had to solve the underlying problem.

This happens in healthcare when a person looks to providers or medications to solve a problem which can only be solved by their own habits, choices, and decisions. A pill, procedure, or prescription is sought in order to overcome obesity. It will work for a short while but not long term. When it fails, more aggressive interventions are tried without addressing the fundamental problem.

The Quick Fix Deception

Senge's business prescription is a good one for healthcare, also. He says, "Beware the symptomatic solution...that address only the symptoms...not fundamental causes, tend to have short-term benefits at best. In the long term, the problem resurfaces and there is increased pressure for symptomatic response. Meanwhile, the capability for fundamental solutions can atrophy". Senge adds, "The _easy solution...the _quick fix...solves the problem temporarily(but) a shifting of burden structure lurks behind many _solutions (and) explains a wide range of behaviors where well-intentioned _solutions' actually makes matters worse over the long term."

Senge and Medicine

The longer a person delays addressing the -real $\|$ cause of their problem, the fewer options and the fewer resources they have for dealing with the -real $\|$ cause of the problem. For instance, the longer a person fails to exercise, often resulting in gaining weight and diminishing heart function, the more difficult effective solutions will be once a person determines to improve their health. If a person continues to -shift the burden $\|$ of their own irresponsibility to another, expecting an artificial solution to relieve the burden created by the rejection of the real solution, they will never achieve their goal. In this case, the harder the patient pushes for solutions from a healthcare system which cannot solve their problem, for which a natural and obvious solution exists, the less benefit the patient will achieve. It is possible to ignore the real solutions – i.e., activity such as walking – until the knees and other joints have deteriorated and it is not possible to become active. In that case, more and more pressure is placed on the artificial system with less and less satisfaction with the results.

Risk Calculators: Dynamic Complexity and Shifting the Burden

These are the reasons for our using risk calculators. Because in a biological system proving the benefit of fundamental solutions by waiting for the negative consequences of poor health choices is not acceptable, we use -risk calculators to project what those poor choices will lead to. Hopefully, those risk calculators will help patients make a decision to make a change.

What If?

Because it takes SETMA only one second (really) to calculate all twelve risk calculators, we thought we were doing great. However, when we showed this function to our new colleagues from Joslin Diabetes Center, Dr. Richard Jackson commented that these scores overstate the risk and Dr. Kenneth Snow asked if we could show the patient how their risk would be affected if they make a change in their habits? Sadly, we had to admit that we could not. That was on Tuesday November 30, 2010.

We realized that while the patient has to know their risk, to understand dynamic complexity and its dangers for their ignoring their health until it is too late, and to avoid shifting the burden of responsibility from themselves to another, their healthcare providers have a responsibility to show them that if they make a change that it will make a difference.

In responding to Drs. Jackson and Snow's questions, SETMA built a -What-Ifl scenario into our display of the Framingham Cardiovascular and Cerebrovascular Risk Score calculations. In the following screen shot, you will see the Risk Calculator Results for a patient with the following information:

- Age 54
- Sex M
- BMI 28.6
- Weight 210
- Height -72
- Cholesterol 212
- HDL 36
- Blood Pressure 144/98
- Diabetes Yes
- Smoker No
- HbA1c 8.1

The General Cardiovascular Disease 10-Year risk

This score projects the probability of a person having a major cardiovascular event such as a heart attack or stroke in the next ten years. The above patient's real heart age is 54 years but the relative heart age is 76 years (his health is deteriorating more rapidly than he is aging), and the 10 year risk is high at 25.3%. These are very discouraging number for a 45 year old man. But now that we have added the –What If? section, we can assure this man that if he will make a change, it will make a difference. In addition, the greatest opportunity for improvement in his risk is indicated by the change in risk with each of the scenarios below.

- If he changes all of the elements in this calculation which are changeable (systolic blood pressure, cholesterol, smoking, hypertension treatment), his risk will improve. The unchangeable features are age, gender and diabetes.
- If he changes all of the elements to -evidenced-based goals, his risk will drop to 9.4% and his -relative heart agell will drop from 80 to 54. These are dramatic improvements in his risk. We can categorically assure him that -if he makes a change, it will make a difference.
- If he changes all of the elements by a 20% improvement, his risk will drop to 15.6% and his —relative heart agel will drop to 64. Obviously these are not as good as the result of treating him to goal, but they are significantly improved.
- The changes for treating his blood pressure to goal without affecting the other elements shows a drop in risk as does changing the cholesterol. There is no improvement for smoking cessation in that it is noted that this patient does not smoke.

Framingham Heart Study R Last Updated/Reviewed 10/03	isk Calculators
General Cardiovascular Disease, 10-Year Risk Total Points Real Heart Age 54 years	Relative Heart Age 16 Total Risk 25.3 % 76 years
WHAT IF?	
All Elements To Goal Overall 20% Improvement Blood Pressure To Goal Lipids To Goal Smoking Cessation (if applicable)	10 9.4 54 13 15.6 64 14 18.4 68 12 13.2 60 0 N/A N/A
Global Cardiovascular Risk Score Total Points	8.4
	A score above 4 indicates increased risk of a cardiovascular event.
Overall 20% Improvement Blood Pressure To Goal Lipids To Goal HgbA1c To Goal Smoking Cessation (if applicable)	1.5 6.0 4.5 6.8 0.0

The second risk score is the Global Cardiovascular Risk Score, which is technically not a Framingham Calculator, bit which was derived from the Framingham Data. It was developed in order to eliminate the unchangeable features such as gender and age which are so heavily weighted in the Framingham Calculators so that many young people with significant risk are overlooked and many elderly people with lower risk are still rated at a very high risk. In addition, while others of the calculators take into consideration whether the patient has diabetes or not, as diabetes is an independent risk factor for heart disease, the Global Cardiovascular Risk Score takes into account whether patients with diabetes are well controlled, or not, as is

indicated by the hemoglobin A1C (HbA1c).

The elements in this score are HDL, Systolic Blood Pressure, HbA1C, packs per day smoking and total cholesterol. As can be seen, if all of these elements are treated to goal, the risk goes from 13.9 points to 0.5 points. It is possible to get some indication of the contribution of each element to the risk by seeing how the risk changes when only one of the elements is changed such as blood pressure, lipids or HbA1C. As is suggested by this review, the most important thing to control is your blood pressure.

Stroke Risk – What IF?

The final calculator for which the -What If? scenarios have been calculated is -stroke risk, which is shown on the template below. The elements of this calculator are:

- Age 55-84
- Systolic blood pressure
- Diabetes mellitus
- Cigarette smoking,
- Prior cardiovascular disease (CHF, MI, Peripheral Vascular Disease, Angina)
- Atrial fibrillation
- Left ventricular hypertrophy
- Use of hypertensive medication

The current calculation of 16% risk is shown and the improvement with each scenario is displayed. Of interest is that simply controlling the blood pressure achieves almost all the possible improvement, i.e., from 16% to 5%. And, there is no difference between a -20% improvement and -a treatment to goal, I demonstrating that it is not necessary to be perfect in order to achieve significant improvement; said another way, -If you make a change – even a small change -- it will make a difference.

Coronary Heart Disease, 10-Year Risk	Total Points	9 Total Ris	k 20 %
WHAT	IF?		,
	Overall 20% Improvement Blood Pressure To Goal Lipids To Goal g Cessation (if applicable)	6 7 4 9	10 13 7 20
Coronary Heart Disease, 2-Year Risk	Total Points	15 Total Ris	k <u>1</u> %
Stroke, 10-Year Risk WHAT	Total Points [10 Total Ris	k <u>6</u> %
	Overall 20% Improvement Blood Pressure To Goal g Cessation (if applicable)	6 8 0	3 4 N/A
Atrial Fibrillation, 10-Year Risk	Total Points	12 Total Ris	k <mark>≥30</mark> %
Stroke After Atrial Fibrillation	Total Points	7 Total Ris	k 9 %
Stroke or Death After Atrial Fibrillation	Total Points	12 Total Ris	k 15 %
Congestive Heart Failure	Total Points	14 Total Ris	- k <u>5</u> %
Hard Coronary Artery Disease, 10-Yea	r Risk Total Points	12 Total Ris	k 10 %
Intermittent Claudication	Total Points	18 Total Ris	k 4 %
Recurring Coronary Heart Disease	Total Points	16 Total Ris	k 11 %

Plan of Care and Treatment Plan

If a patient is going to make a change which will make a difference, there must be a basis on which change can be expected. We know that conversations at the time of an office visit are part of that decision to make a change. However, without a written, personalized plan of care and treatment plan, few patients will successfully make those changes and sustain them.

The -WHAT-IF? I scenarios described above will be added to patients' diabetes, hypertension and/or lipid plans of care and treatment plans. These documents are the -batons I which are passed from one member of the healthcare team – your healthcare provider – to another member of the team – the patient. If the patient will study these documents, we believe it will encourage them to make changes and it is our confidence that those changes will make a difference. With the patient's name and personal data in each plan, the probability of their studying the material is greatly increased.

SETMA Tutorial For Use of Framingham Risk Calculators

The SETMA Framingham Heart Risk Calculators can be found on the following Disease-Management Master Templates:

- Diabetes,
- Lipids,

- Hypertension
- CHF
- Acute Coronary Syndrome
- Chronic Stable Angina

This is an illustration taken from the Lipids Disease Management Tool:

Lipids	and the second second			nt Larry ge 54	Sex M	fest		Navigation • Lipids • General
	's Lipid Philos	sophy				Transverse and		Home
Compliance	-		Most Recent L	abs Go	als	Risk Factors Coronary Heart Disea		Lipids System Review
Last Lipid	04/04/201		Check for	or New La	bs	MI (Heart Attack)	150	Extremity Exam
Last CRP			Cholesterol	212	09/13/2013	Angina		
Last Liver Pane	72.00		HDL	36	09/13/2013	CABG		Eye Exam
Height Weight	210.00	inches	Cholesterol/HDL	5.89		Non-Coronary Atherosch Peripheral Artery I		Cardio Exam
BMI	28.58	pounds	Triglycerides	193	09/13/2013	Cerebrovascular		Lifestyle Changes
Body Fat	38.9	%	Trig/HDL Chudemierene	5.36 +				
BMR		cal/day	Chylomicrons CPK		11	Framingham Risk Scores		Lipids Plan
Protein Reg	114	grams/day		155	09/13/2013	10-Year General Risk	25.3 %	
Waist	40.00	inches	VLDL		,	10-Year Stroke Risk	6 %	Lipoprotein Metabolism
Blood Pressure			LDL-Remnant	í –	Info	Global Cardio Score	8.4 pts	Summary of Lipid Studies
144 /	98 m	mHa	Homocystiene	22	04/04/2012			Biomarkers of Atherosclerosis
144 /		mHq	hsCRP	4.9	04/04/2012	Female Age > 45		Lipoproteins
1	m	mHg	Apo A1			Hypertension > 140/9	10	Significance
Diabetes Mellitu	is + 🕫	- 0	Apo E2			Blood Pressure Medi	cations	Composition
Metaboilc Synd	rome + 🖲	. 0	Apo E4	I		Smoking HDL		Classification
			L	abs Over	Time	Male < 40		Hyperlipoproteinemias
Fredrickson	n Classifica from Labs	tion	VAP Test Resu	Ilts	11	Female < 50		Hypolipoproteinemias
		_	Apo B			FHx Premature HD		VLDLs
	NOV		HDL 2	-		Male First Degree		IDLS
Help	Info		HDL 3			Female First Degr	ee < 65	LDLs
			HDL Chol V	AP		Assessment Update		HDLs
Last Updated/R			IDL			Aggressive measures taken to lower LDL to b		LDL Receptors
	04/30/	2013	IDL VLDL 3			Last Updated/Reviewed	CIOW 70.	Chylomicrons
			LDL 1 Pat A				2/2013	Chylomicrons and Triglycerides
			LDL 2 Pat A					ondary Causes of Abnormal Lipid
			LDL 3 Pat B				5000	Hypercholesterolemia
			LDL Pat 4 B	100				Hypocholesterolemia
			LDL Chol VA					Low HDL
			LDL Density	-				Hypertriglyceridemia
			LUL Real C					

The three major Risk Score results – 10-Year General Cardiovascular Risk, 10-Year Stroke Risk and the Global Cardio Score -- are displayed on each master templates. When the button entitled **Framingham Risk Scores** is depressed on any of the above named master templates, the Framingham Heart Risk Calculator is launched. Without any other action on the provider's part, all twelve calculations are made. All data points are aggregated electronically for this purpose.

SETMA's deployment of the Risk Calculators (in the order of their display) includes:

- General Cardiovascular Disease, 10 Year Risk
- Global Cardiovascular Risk Score (Not a Framingham Score but built on their data)
- Coronary Heart Disease 10 Year Risk

- Coronary Heart Disease 2 Year Risk
- Stroke, Ten Year Risk
- Atrial Fibrillation, 10 Year Risk
- Stroke After Atrial Fibrillation
- Stroke or Death after Atrial Fibrillation
- Congestive Heart Failure
- Hard Coronary Artery Disease, 10 year Risk
- Recurring Coronary Heart Disease
- Intermittent Claudication

The following is the template which appears when the button entitled **Framingham Risk Scores** is depressed. It will be noted that the titles of each of the risk calculators is in blue. This means that each is a hyperlink and when depressed the elements on the basis of which the score is calculated is displayed.

This function is a useful teaching tool, as it possible to review these elements with a patient when any score is being discussed. This will be a useful means of alerting patients to the changes they need to make in their lifestyles or treatment regimens in order to moderate their risk. The date that the Framingham Risk Scores were calculated and reviewed is noted at the top of the template.

Coronary Heart Disease, 10-Year	Risk Total Points	9	Total Risk	20	%
ļ	WHAT IF?				
S	Overall 20% Improvement Blood Pressure To Goal Lipids To Goal Smoking Cessation (if applicable)	7 4		10 13 7 20	
Coronary Heart Disease, 2-Year I	Risk Total Points	15	Total Risk	1	%
<u>Stroke, 10-Year Risk</u>	Total Points WHAT IF?	10	Total Risk	6	%
5	Overall 20% Improvement Blood Pressure To Goal Smoking Cessation (if applicable)	8		3 4 N/A	
Atrial Fibrillation, 10-Year Risk	Total Points	12	Total Risk	>30	%
Stroke After Atrial Fibrillation	Total Points	7	Total Risk	9	%
Stroke or Death After Atrial Fibri	illation Total Points	12	Total Risk	15	%
Congestive Heart Failure	Total Points	14	Total Risk	5	%
Hard Coronary Artery Disease, 1	0-Year Risk Total Points	12	Total Risk	10	%
Intermittent Claudication	Total Points	18	Total Risk	4	%
Recurring Coronary Heart Diseas	se Total Points	16	Total Risk	11	%

The remainder of this tutorial will be a review of the elements of each of the risk scores with an introductory statement for each, taken from the Framingham official website at <u>www.framinghamheartstudy.org</u>, followed by SETMA's display of the risk elements when the hyperlinks above are launched.

The introductory material includes:

• Title of risk calculator

- Source from which it is taken
- Outcome which is the end-point for the risk calculation
- Duration of follow-up
- Population of interest
- Predictors

General Cardiovascular Disease (10-Year Risk)

(D'Agostino, Vasan, Pencina, Wolf, Cobain, Massaro, Kannel. 'A General Cardiovascular Risk Profile for Use in Primary Care: The Framingham Heart Study', *Circulation* 2008)

Outcome -- CVD (coronary death, myocardial infarction, coronary insufficiency, angina, ischemic stroke, hemorrhagic stroke, transient ischemic attack, peripheral artery disease, heart failure)

Duration of follow-up -- Maximum of 12 years, 10-year risk prediction

Population of interest -- Individuals 30 to 74 years old and without CVD at the baseline examination

Predictors -- Age, Diabetes, Smoking, Treated and untreated Systolic Blood Pressure, Total cholesterol, HDL cholesterol, BMI replacing lipids in a simpler model.

Framingl General Cardiovasc	ham Heart Stu sular Disease	
Predictors Age, Sex Systolic Blood Pressure	Values 54 M 144	Points 8 2
Hypertension Treatment Cholesterol HDL Diabetes Smoker	No 212 36 Yes No	2 1 3 0
Relative Heart Age Based on this risk score, ye	To	I Points 16 tal Risk 25.3 % 76 years.
ОК	Cancel	

Global Cardiovascular Risk Score

This is the only risk calculator which was not published by the Framingham Heart Study. It is a modification of the risk calculator based on the Framingham data but with the elimination of age and gender. The rationale for this was that the weight of age in the Framingham study was so great that it underestimated the cardiovascular risk in the young and overestimated it in the elderly.

The Global Cardiovascular Risk Score eliminates the age and gender bias and gives a more accurate estimate of the relative risk of al groups without regard to age. The following is the pop-up which appears when the Global Cardiovascular Risk hyperlink is launched.

Global Cardio Last Updated/	Reviewed 09/19/2013
Enter each of the five parameters be You may click "Import" to pull the value	
Cholesterol	212.0
HDL	36.0
HgbA1c Im	port >> 8.1
Systolic BP	144
Packs Per Day	0
Calculate	8.4 points

Coronary Heart Disease 10-Year Risk

(based on Wilson, D'Agostino, Levy et al. 'Prediction of Coronary Heart Disease using Risk Factor Categories', *Circulation* 1998)

Outcome -- Coronary Heart Disease

Duration of follow-up -- Maximum of 12 years, 10-year risk prediction

Population of interest -- Individuals 30 to 74 years old and without overt CHD at the baseline examination

Predictors – Age, Diabetes, Smoking, JNC-V blood pressure categories, NCEP total cholesterol categories, LDL cholesterol categories,

Framingha Coronary Heart [am Heart Study Disease, 10-Yea	r Risk
Predictors	Values	Points
Age, Sex	54 M	3
Blood Pressure	144 / 98	2
Cholesterol	212	1
HDL	36	1
Diabetes	Yes	2
Smoker	No	0
	Total Points	9
	Total Risk	20 %
Comparative Risk		
Patients in your age range, 50	, who were considered to	be at
"low risk" had a total risk	of <u>6</u> %.	
"average risk" had a tota	Irisk of 14%.	

Coronary Heart Disease (2-Year Risk)

(D'Agostino, Russell MW, Huse DM et al. 'Primary and subsequent coronary risk appraisal: new results from the Framingham Study', *American Heart Journal* 2000)

Outcome -- First Coronary Heart Disease

Duration of follow-up -- Maximum of 4 years, 2-year risk prediction score sheets **Population of interest --** Individuals free of all of the following CVDs before examination; CHD (includes myocardial infarction, coronary insufficiency, and angina pectoris); stroke (ischemic or hemorrhagic); transient ischemic attack; congestive heart failure; intermittent claudication **Predictors** – Age, Systolic blood pressure (SBP), Cigarette smoking status (1 if current smoker,

0 otherwise), Fasting lipid level (totals and HDL Cholesterol), Physician diagnosis of diabetes at the current or a previous examination, Use of antihypertensive medication (yes/no),

Disease, 2-Ye	/ ar Risk
Values	Points
54 M	4
No ge, sex calculation.	
144	2
No	
212 , 36	6
Yes	3
No	0
0 oz/week	0
Total Poir Total Ri	
	Values 54 M No ge, sex calculation. 144 No 212 , 36 Yes No 0 oz/week

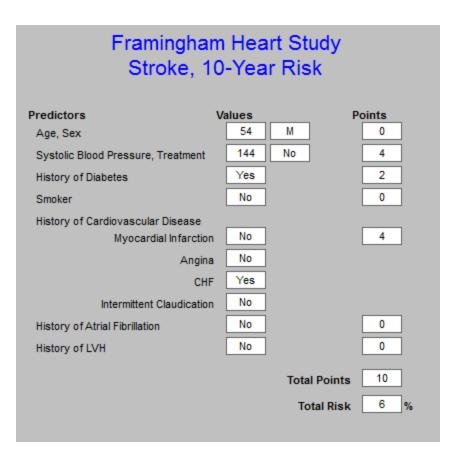
Stroke

(D'Agostino, Wolf, Belanger, Kannel 'Stroke Risk Profile: Adjustment for Antihypertensive Medication', *Stroke* 1994)

Outcome -- Stroke

Duration of follow-up -- 10 years

Population of interest -- Individuals aged 55 to 84 years, free of stroke at baseline **Predictors** - Age, Systolic blood pressure, Diabetes mellitus, Cigarette smoking, Prior cardiovascular disease, Atrial fibrillation, Left ventricular hypertrophy, Use of hypertensive medication



Atrial Fibrillation (AF) (10-year risk)

(Schnabel RB, Sullivan LM, Levy D, Pencina MJ, Massaro JM, D'Agostino RB, Sr., Newton-Cheh C, Yamamoto JF, Magnani JW, Tadros TM, Kannel WB, Wang TJ, Ellinor PT, Wolf PA, Vasan RS, Benjamin EJ. Development of a risk score for atrial fibrillation (Framingham Heart Study): a community-based cohort *Lancet* 2009;373:739-745.)

Outcome -- First AF

Duration of follow-up -- Maximum of 12 years, 10-year risk prediction score sheets **Population of interest** -- Participants free of AF at baseline, aged 45 to 95 years **Predictors** – Age, Male sex, Body mass index, Systolic blood pressure, Treatment for hypertension, PR interval, Significant murmur, Prevalent heart failure

Framingham Heart Study Atrial Fibrillation, 10-Year Risk

Predictors	Values	Points
Age, Sex	54 M	2
Systolic Blood Pressure	144	0
Hypertension Treatment	No	0
Body Mass Index	28.58	0
PR Interval		0
Age, Murmur Presence	No	0
Age, Heart Failure Presence	Yes	10
	Total F	Points 12
	Tota	IRisk >30 %
ОК	Cancel	

Stroke After Atrial Fibrillation

(Wang, Massaro, Levy et al. 'A Risk Score for Predicting Stroke or Death in Individuals with New-Onset Atrial Fibrillation in the Community', *JAMA* 2003)

Outcome -- Stroke

Duration of follow-up -- Maximum of 10 years; mean 4 years; 5-year risk estimated **Population of interest** -- 705 individuals aged 55 - 94 years from the Original and Offspring Cohorts of the Framingham Heart Study meeting the following criteria: had an occurrence of new-onset Atrial Fibrillation (AF) not treated with warfarin at baseline did not have a stroke, transient ischemic attack (TIA), or death within 30 days of AF diagnosis without rheumatic mitral stenosis

Predictors - Age, Gender, Systolic blood pressure, Diabetes, Prior stroke or ischemic attack

	gham Heart Stud fter Atrial Fibrillat	-
Predictors Age Sex	Values 54	Points 0
Systolic Blood Pressure History of Diabetes	144 Yes	2
History of Stroke or TIA	No	0
	Total	
(OK Cancel	

Stroke or Death After Atrial Fibrillation

(Wang TJ, Massaro JM, Levy D, Vasan RS, Wolf PA, D'Agostino RB, Larson MG, Kannel WB, Benjamin EJ. A risk score for predicting stroke or death in individuals with new-onset atrial fibrillation in the community: the Framingham Heart Study. *JAMA*. 2003;290:1049-1056.)

Outcome -- Stroke or death

Duration of follow-up -- Maximum of 10 years; mean 4 years; 5-year risk estimated **Population of interest --** 705 individuals aged 54 - 94 years from the Original and Offspring Cohorts meeting the following criteria: had an occurrence of new-onset Atrial Fibrillation (AF) not treated with warfarin at baseline did not have a stroke, transient ischemic attack (TIA), or death within 30 days of AF diagnosis without rheumatic mitral stenosis

Predictors - Age, Gender, Systolic blood pressure, Prior stroke or ischemic attack, Diabetes

Framingham Heart Study Stroke or Death After Atrial Fibrillation

Predictors	Values	Points
Age, Sex	54 M	0
Systolic Blood Pressure	144	2
Diabetes	Yes	4
Smoker	No	0
Prior Myocardial Infarction	No	6
Congestive Heart Failure	Yes	
Heart Murmur	No	0
LVH Present	No	0
	Total Po	pints 12
	Total	Risk 15 %
ОК	Cancel	

Congestive Heart Failure

(Kannel, D'Agostino, Silbershatz, Belanger, Wilson, Levy. 'Profile for Estimating Risk of Heart

Failure' - Arch Intern. Med. 1999)

Outcome -- Congestive Heart Failure

Duration of follow-up -- Maximum of 38 years, 4-year risk prediction (pooled logistic regression)

Population of interest -- Individuals 45 to 94 years old with coronary disease, hypertension or valvular disease

Predictors – Age, Left Ventricular Hypertrophy, Heart rate, Systolic Blood Pressure, Coronary Heart Disease, Valve Disease, Diabetes, BMI, Vital Capacity (some models), Cardiomegaly (some models)

54 144 28.58 98.00 Yes]]]]	M		1
28.58 98.00]]]			0
98.00]			
	1			0
Yes				4
				8
No				0
No				0
Yes]			1
		Total		s 14
	No	No	No	No

Hard Coronary Heart Disease

(The Adult Treatment Panel III, JAMA. 2001)

Outcome -- Hard coronary heart disease (HCHD) (myocardial infarction or coronary death) **Duration of follow-up** -- Maximum of 12 years with risk calculated at 10 years **Population of interest** -- Individuals free of CHD, intermittent claudication and diabetes, 30-79 years of age

Predictors - Age, Total cholesterol, HDL, SBP, Treatment for hypertension, Smoking status

Framingham Heart Study Hard Coronary Artery Disease, 10-Year Risk						
Predictors	Values	Points				
Age, Sex	54 M	6				
Systolic Blood Pressure	144	1				
Hypertension Treatment	No					
HDL	36	2				
Cholesterol	212	3				
Smoker	No					
	Total F	Points 12				
	Tota	IRisk 10 %				
ОК	Cancel					

Recurring Coronary Heart Disease

(D'Agostino, Russell MW, Huse DM et al. 'Primary and subsequent coronary risk appraisal: new results from the Framingham Study', American Heart Journal 2000)

Outcome -- Subsequent CHD (includes mostly hospitalized events consisting of myocardial infarction, coronary insufficiency, angina pectoris, and sudden and non-sudden coronary death) **Duration of follow-up --** Maximum of 4 years, 2-year risk prediction

Population of interest -- Individuals who had at least one CHD event or ischemic stroke before examination and survived the acute stage of that event.

Predictors – Age, Systolic blood pressure (SBP), Cigarette smoking status (1 if current smoker,

0 otherwise), Fasting lipid level (total and HDL cholesterol), Physician diagnosis of diabetes at the current or a previous examination

Framingham Heart Study Recurring Coronary Heart Disease

Predictors	Values	Points
Age, Sex	54 M	4
Cholesterol	212	8
HDL	36	
Diabetes	Yes	4
Female Only Indicators		
Smoker	No	0
Systolic Blood Pressure	144	0
	7-4-1 0	oints 16
	Total P	
	Total	Risk 11 %
	Cancel	

Intermittent Claudication (IC)

(Murabito, D'Agostino, Silbershatz, Wilson 'Intermittent Claudication: A risk profile from the Framingham Heart Study', Circulation 1997)

Outcome -- Intermittent Claudication

Duration of follow-up -- 4-year intervals pooled for a total of 38 years **Population of interest --** Individuals free of IC at the baseline examination **Predictors** – Age, Sex, Serum cholesterol, Hypertension, Cigarette smoking, Diabetes, Coronary heart disease

Framingham Heart Study Intermittent Claudication					
Predictors Age Sex Blood Pressure Cholesterol Diabetes Cigarettes Per Day Coronary Heart Disease	Values 54 M 144 / 98 212 Yes Yes	Points 1 3 2 2 5 0 5			
<u></u> 0K	т	al Points 18 otal Risk 4 %			

Important Note for SETMA's use of the Framingham Heart Study Calculator

Left Ventricular Hypertrophy -- LVH

Because all of the data for the Framingham Risk Score calculations is aggregated from SETMA's EMR data base, it is important that all of the data points be present which are required

for their accurate calculation.

LVH is the most problematical element and one of the most important. LVH leads to a fivefold to 10-fold increase in cardiovascular risk in hypertensive patients. It is usually the response to a chronic volume or pressure load. The two most important pressure overload states are systemic hypertension and aortic stenosis. The following methods can be used to determine LVH:

1. **Electrocardiogram (ECG)** – LVH can produce five major ECG changes: increased QRS voltage; increased QRS duration; left axis deviation; repolarization (ST-T) changes; and left atrial abnormality. The major criteria used in the ECG diagnosis of LVH are:.

a. Sokolow-Lyon indices — There are two criteria with these widely used indices: Sum of S wave in V1 and R wave in V5 or V6 3.5 mV (35 mm) and/or R wave in aVL 1.1 mV (11 mm)

b. Cornell voltage criteria — These criteria are based upon echocardiographic studies

designed to detect a LV mass index >132 g/m2 in men and >109 g/m2 in women.

- 1) For men: S in V3 plus R in aVL >2.8 mV (28 mm)
- 2) For women: S in V3 + R in aVL >2.0 mV (20 mm)

2. Echocardiogram – This study is needed for a comprehensive assessment of LVH in order

- to determine cardiovascular risk in hypertensive patients
- 3. Cardiac Catherization

4. Pro-BNP – the left ventricular mass can be shown to be increased when the proBNP is at or above 35 pg/ml

The documentation of LVH in SETMA's data base is found on the Cardiac History template. This template can be found by the following steps:

From the Master GP Template, the Navigation Button entitled History is depressed

PDM NURSE HISTORIES HI	EALTH Q	UIZES HPI		X-RAY ASSESS PLAN		Home
Chart QTest	43 Year	s M	Visit Type	Facility	Payor	Nursing
	45 Tear	5 M	_ PC		<u> </u>	Histories
Chief Complaints <u>Comment</u>			PU	BP D	1/1	
2	Dation	t Goal This	Visit		0	Health
3	Patien	it Goar This	VISIL	Temp	1	Lab Results
4				Pulse Resp		Questionnaires
5				Weight (lb)		HPI Chief
6				BMI		
				Body Fat		System Review
Chronic Conditions Archive Re-Order	HCC Rx I		d HPI-1.2	BMR Cardiac Risk Ratio		Physical Exam
1		11	HPI-1,2	Fall Risk Assessme	nt //	Radiology
3		11	HPI-3,4	Functional Assessme		Assessment
4		11		Pain Assessment	11	Hydration
5		11	HPI-5,6	Stress Assessmen	t //	
6		11		Wellness Assessme	nt //	Nutrition
7		11	HPI-7,8	Nutrition Assessme	nt //	Exercise
8		11		Sleep Questionnair		Plan
9		11	HPI-9,10	Depression Screer		Procedures
10		11		Karnofsky/Lansky		
11		11	HPI-11,12	Palliative Perf Scale		Chart Note
12		11		Braden Scale		
13		11	HPI-13,14	FAST Assessment		
14		11		Clinic Performa	nce Measures	
15		11	HPI-15,16	X Alert		
16		11	HPI-17,18	Allergies		
18		11	HE1-17,10	Comments		
19		11	HPI-19,20	E-Mail Note	HIPAA	
20		11		Telephone		
21		11		Vitals/Time		
22		11		Nursing Home		
23		11		HCC Reviewed Tod	ay	
24		11		Last Reviewed / /	·	
25		11				

RDM NURSE <u>HISTORIES</u> HEALTH	QUIZES HPI	ROS	P.E.	X-RAY	ASSESS	PLAN	PROCS
Reviewed pt's history today	Child						
Source	r						E
Habits	Hospital						
Tobacco Alcohol Drugs Caffeine Exercises regularly Toxic Substances							
Exercises regularly	Surgical						
Habit Details Living Arrange/Assist Devices	-						E
Social Ethnicity Occupation Sexuality Marital Status	Previous Illness						
Family Adopted Unknown							
Social History Past History	Family Histo		Cardia	c History	Con	nments]

From the History template the **Cardiac History** button is depressed

On the Cardiac History template, the documentation of the LVH is found. This is the point from which the presences or absences of LVH is determined for the Framingham Scores.

			Cardiac His	story		
🔲 MI (Heart /	Attack)				CABG	
Date		Туре			Date	
Stents					Permena	int Pacemaker
		Loc			Date	11
	Hear	t Cath				
	Ĩ		O No Intervention	C Medical Intervention C Medical Intervention C Medical Intervention	 PTCA PTCA PTCA PTCA 	
			ОК	Cancel		

It is very important to denote whether or not your patient has LVH in order for the Framingham

Risk scores to be accurate.

The Value of Framingham Calculators

In August, 2010, the *American Family Physician* (reference: *Global Risk of Coronary Heart Disease: Assessment and Application*, Anthony J. Viera, MD, MPH and Stacey L. Seridan, MD, MPH, University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, North Carolina *Am Fam Physician*. 2010 Aug 1;82(3):265-274) made the following observations:

-Coronary heart disease is the most common cause of death in the United States. The conventional risk factor approach to primary prevention excludes many patients who could benefit from preventive therapies. A global risk approach allows more accurate estimates of risk to guide clinical primary prevention efforts. Global risk of coronary heart disease is a calculation of the absolute risk of having a coronary heart disease event (e.g., death, myocardial infarction) over a specified period. It is based on an empiric equation that combines major risk factors, such as blood pressure and cholesterol levels. When physicians know a patient's global risk of coronary heart disease, they are more likely to prescribe risk-reducing therapies such as antihypertensives, statins, and aspirin. In addition, patients who know their risk level are more likely to initiate risk-reducing therapies. Many tools are available to

estimate global risk, including several Web- based calculators. In the United States, tools based on the Framingham Heart Study are recommended.

Current Best Practices for Presenting Global CHD Risk Information to Patients

• Global CHD risk should be presented with comparative information for persons of the same age and sex who have no risk factors

• In addition to presenting the absolute risk as a percentage, consider presenting in other numerical formats (e.g., number of persons per 1,000 over a specific period) or picture format (e.g., number of smiley/sad faces out of 100 persons)

• Rather than categorizing risk as low, moderate, or high, a person's risk should be placed in the

context of what is considered an actionable level.

• Global CHD risk should be presented in isolation of other risks (or with emphasis on the CHD risk)

• Global CHD risk should be presented with information about controlling risk

• Global CHD risk appears to be more influential when presented by physicians (as opposed to non-physician personnel or a computer program)

Suggested Thresholds for Interventions for Primary Prevention of CHD

Absolute risk of hard CHD event over 10 years					
Intervention	≤ 5%	6 to 10%	> 10%	≥ 20%	
Lifestyle modifications*	Yes	Yes	Yes	Yes	
Blood pressure-lowering medication	Yes†	Yes	Yes	Yes	
Aspirin chemoprevention‡	No	Consider	Yes	Yes	
Statin therapy	No	Consider	Consider	Yes	

Smoking cessation counseling and pharmacologic aides

Any patient who smokes

Cardiovascular Disease Risk Factors

There are three categories of cardiovascular disease risk factors: major, independent risk factors;

predisposing risk factors; contributing risk factors.

The Major Independent Risk Factors

These are the risk factors which will contribute to the causation of heart disease directly and without the influence of any other condition. It is imperative to eliminate these factors either by lifestyle changes or by medication if required for control.

- **Cigarette smoking** without the commitment to stopping smoking, a person CANNOT support any claim to the desire to maintain, improve, or restore their health. The first requirement to stop smoking is a decision and personal commitment to quit.
- Elevated blood pressure remember, if you are 55 years of age, and if you DONOT have high blood pressure, your life time risk of developing high blood pressure is 90%, if you do not take steps to avoid its development. These steps include diet, exercise, stopping smoking, etc. The first step is to have a medical examination with your blood pressure being taken properly and repetitively.
- Elevated serum total (and LDL) cholesterol you cannot know your LDL without a blood test which must be taken while fasting. Once you know you have elevated LDL, you will require lifestyle modification weight loss, exercise and stopping smoking and probably will require medication.
- Low serum HDL cholesterol -- you cannot know your HDL without a blood test. Once you know that your HDL is low, you will require an exercise program and medication to raise it.
- **Diabetes mellitus** if you have diabetes, you can't —get rid of it, but you can successfully live with it through education, discipline and excellent healthcare. It is critical that you know and remember your hemoglobin A1C number and that you collaborate with your healthcare provider to improve it until it is consistently below 6.0.
- Advancing age there is only one way to stop getting older and that is not acceptable to any of us. However, you can –age well by the choices you make. And, even if you have made bad choices in the past, you can reverse many of the effects of those choices with lifestyle changes and medical attention.

Predisposing risk factors

These factors work with other risk factors to produce heart disease and vascular disease. They are important but not as critical as the risk factors above. It is not possible to ignore obesity as a risk factor for heart disease but if you have o choose between losing weight and stopping smoking – stop smoking.

- **Obesity** the bad news is that any level of overweight or obesity is harmful to your health. The Good news is that you don't have to be at your ideal body weight to improve your health. A twenty-pound weight loss can make a huge difference, even if you are greatly obese.
- **Abdominal obesity** the focus of our attention on obesity must be the fat around the waist and abdomen. It is the fat cells around our abdomen which produces harmful substances which contribute to heart disease and illness.
- **Physical inactivity** a sedentary lifestyle is a greater risk factor for the development of congestive heart failure than having diabetes. Most people can't make a decision about whether they are going to have diabetes or not, but you can make the decision to take a daily, 30-minute brisk walk.
- Family history of premature coronary heart disease you can't choose your parents

or grandparents, but if they have or had heart disease you can pay closer attention to your own health and the modifiable risk factors over which you do have control.

- Ethnic characteristics as with your ancestors, you cannot choose your ethnicity, but if your race increases your risk of heart disease, you can control other factors more aggressively.
- **Psychosocial factors** living a stressful lifestyle and/or not dealing with stress constructively will increase your risk of heart disease.

Conditional risk factors

These are risk factors whose significance is not totally know and/or which are not the primary focus of strategies to prevent heart disease. However, when the other factors are controlled or while they are being controlled, these factors will either be being improved or can be given attention. All of them require specialized blood tests which are readily available. They should be part of your evaluation if you are serious about your health. Insurance will not always pay for these tests which will test your seriousness about your health as you determine how you will use your discretionary income.

- Elevated serum triglycerides this value will be determined when your lipids are measured by your doctor. If your levels are very high, they can be improved by controlling your diabetes, or by changing your diet if you are not diabetic. Excessive, non-fibrous, simple carbohydrates contribute to elevated triglyceride levels.Small LDL particles – diet, exercise and medication can change the size of your LDL.
- It is not only the total value of your LDL which is important but the size of the particles. Small particles have a greater effect on the development of heart disease than larger LDL particles.
- Elevated serum homocysteine this is determined by a simple blood tests and responds to treatment if it is elevated. While presently not paid for by some insurance plans, it will be some day. It is important for you to know your value and to decrease it if it is high.
- Elevated serum lipoprotein(a) -- Lp(a) is predominantly a genetic trait whose level remains more or less constant after puberty. Levels of greater than 30mg/dl have been demonstrated to independently increase the risk of CHD by six fold. Lp(a) verbalized as -Lp _little a. 'l is a modified form of LDL. When both Lp(a) and LDL are elevated, the patient has a particularly high risk of developing coronary disease. Reduction of LDL and Lp(a) is associated with a reduction in clinical events and disease severity. Most of the lifestyle modifications (diet, exercise) and pharmaceutical agents known to reduce cholesterol have little or no effect on Lp(a) concentration. Fish oil-based diets have shown some ability to reduce Lp(a) levels, while niacin and N-acetylcysteine have shown (NAC), in certain studies, a pronounced ability to reduce Lp(a) levels.
- **Prothrombotic factors (eg, fibrinogen)** -Prothrombotic means an increased possibility of forming blood clots. There are a number of -factors, proteins or substances in the blood which increase the risk of developing a blood clot. It must always be remembered that blood clotting or not clotting is a delicate and critical balance. If your blood cannot or will not clot, you will bleed to death; if your blood clots to readily, you will die of a heart attack or other abnormal blood clotting. Normally, this clotting/not- clotting is kept in balance naturally, but in disease

processes or abnormal circumstances it is not. More people have a problem with too much clotting than with not clotting enough which is why an aspirin-a-day is recommended for diabetics and those with risk factors for heart disease. Measuring your serum fibrinogen levels, uric acid, calcium, magnesium, plasminogen activator inhibitor, d-dimer, platelet count and other tests will help your healthcare provider give you an estimate of whether you have a prothrombotic state and what you can and should do about it.

• Inflammatory markers (eg, C-reactive protein) – There are a number of inflammatory makers in the body. Heart specific C-reactive protein, which goes up naturally when you have an infection, is an emerging risk factor which may become a major independent risk factor in years to come. All of the inflammatory makers are part of the Cardiometabolic Risk Syndrome which was previously called –insulin resistance syndrome, I –syndrome XI or the –metabolic syndrome. I Whether you have this syndrome is easy for your healthcare provider to determine with simple blood tests and a well-established equation.

The following is a partial list of patient factors which contribute to less than optimal healthcare in the United States today:

- Lifestyle Inactivity, poor diet, overeating, smoking, excessive alcohol consumption. Much more than genetics, lifestyle often adversely affects patient health.
- Access to healthcare There are groups of people who have limited access to healthcare. Others cannot afford the healthcare which has been recommended. Either cause decreases or even eliminates the potential health benefit of care.
- Adherence Patient non-adherence with prescribed treatment plans is a major problem.

When patient fail to take their medications, follow-up with care as recommended or follow-through with treatment recommendations, they limit the benefit they could have received.

- **Refusal** There is a difference between adherence and refusal to accept a treatment recommendation. The second most common reason for internet searches is question about healthcare. The problem is that while patients are getting more information than ever before, often that information is invalid.
- **Complacen cy** The failure of patients to seek care or to follow known beneficial care. Very often patients don't feel badly and as a result are unwilling to engage in uncomfortable, complicated and sometimes expensive care which can interfere with their lifestyles. The problem is that most of the illnesses which can be treated successfully but which can kill you if they aren't, don't have significant symptoms until irreversible damage has been done to your body.

Boiled Frog Analogy

The boiled-frog analogy has often been used to illustrate the reluctance of people to change their behavior because they are not uncomfortable. The analogy describes a frog which is placed in a pot of cool water. The frog is comfortable and senses no danger. When the pot is placed on a stove and heat is applied, the change is so gradual that the frog is not aware of the danger until it is too late. The frog boils to death. This is not unlike a patient who complains, —But, I was fine yesterday, why am I unable to move my left arm today? The reason is that the patient did not take their blood pressure medication and did not control their weight and did not stop smoking until it was too late. The cause of the stroke started many years before the actual event. By the way, it is NEVER -too late to begin making changes. Recent research has shown that smokers who are diagnosed with lung cancer live longer and are more comfortable if they stop smoking than are the patients who are diagnosed with lung cancer and continue to smoke. It is NEVER too late to quit smoking.

Creating Discomfort in Patients

The problem remains as to how to change patient behavior. This was a problem for providers as well. The tendency of healthcare providers not to -change, I is called -treatment inertia. If is the inclination not to change things even when patients are not treated to goal. In addressing this, SETMA began publicly reporting provider performance by provider name. This created discomfort in the providers and has had a positive effect on the quality of care patients are receiving.

But, how do we make the patient uncomfortable enough that they will make and sustain changes in their lifestyles and compliance with a plan of care? One of the ways is with —risk stratification.

The calculation of a patient's risk of developing significant health problems and the showing of that calculation to the patient is one way SETMA attempts to encourage patients to make and sustain change. SETMA uses many tools to evaluate patient health risk. All are described on SETMA's website at <u>www.jameslhollymd.com</u> under the heading *Electronic Patient Management Tools*.

Two categories of risk tools are described there, under the following titles:

Preventive Heath Tools

- LESS Initiative
- Smoking Cessation
- Exercise
- Diabetic Exercise
- CHF Exercise
- Preventing Diabetes
- Preventing Hypertension
- Weight Management

Framingham Cardiovascular Risk

- Cardiometabolic Risk Assessment
- LDL Levels

- Fredrickson Classification of Dyslipidemia Lipid Disease Management •
- •
- Framingham Heart Study Risk Calculators •