2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

November 21, 2014

12:30pm - 1:30pm ET

Agenda

Time (ET)	Agenda Item / Topic	Speaker / Facilitator
12:30 – 12:35	Welcome and Introductions	Laura King Hahn, American Heart Association, Program Initiatives Manager, The Collaboration for Heart Disease and Stroke Prevention
12:35 – 12:40	Million Hearts® Description of the ABCS	Laura King Hahn, American Heart Association
12:40 – 1: 15	Controlling Cholesterol: Guidance for Use & Implications for Primary Care Practitioners	Dr. Neil J. Stone, MD, MACP, FAHA, FACC Northwestern University Feinberg School of Medicine Chair, ACC/AHA Prevention Guideline 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines
1:15 – 1:25	Q and A	Laura King Hahn, American Heart Association
1:25 – 1:30	Final Remarks	Laura King Hahn, American Heart Association

Welcome & Introductions
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Description of the ABCS

Laura King Hahn, American Heart Association
Program Initiatives Manager
The Collaboration for Heart Disease and Stroke Prevention
(Supporting the Million Hearts Initiative)

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Goal: Prevent 1 million heart attacks and strokes by 2017

- US Department of Health and Human Services initiative, co-led by:
  - Centers for Disease Control and Prevention (CDC)
  - Centers for Medicare & Medicaid Services (CMS)
- Partners across federal and state agencies and private organizations

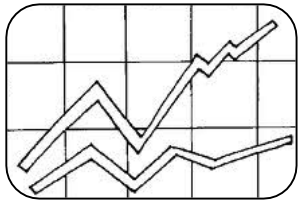
Key Components of Million Hearts®

Keeping Us Healthy
Changing the environment

Health Disparities

Excelling in the ABCS
Optimizing care

Focus on the ABCS



Health tools and technology

Innovations in care delivery

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Glantz. Prev Med. 2008; 47(4): 452-3.
How Tobacco Smoke Causes Disease: A Report of the Surgeon General, 2010.

The ABCS to Prevent Heart Attacks and Strokes

Aspirin	People who have had a heart attack and stroke who are taking aspirin
Blood pressure	People with hypertension who have adequately controlled blood pressure
Cholesterol	People with high cholesterol who are effectively managed
Smoking	People trying to quit smoking who get help

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Sources: National Ambulatory Medical Care Survey, National Health and Nutrition Examination Survey

Getting to Goal

Intervention	2009-2010 Measure Value	2017 Target	Clinical target
Aspirin for those at risk	54%	65%	70%
Blood pressure control	52%	65%	70%
Cholesterol management	33%	65%	70%
Smoking cessation	22%	65%	70%
Smoking prevalence	26%	10% reduction (~24%)	
Sodium reduction	3580 mg/day	20% reduction (~2900 mg/day)	
Trans fat reduction (artificial)	0.6% of calories	100% reduction (0% of calories)	

Sources: National Ambulatory Medical Care Survey, National Health and Nutrition Examination Survey, National Survey of Drug Use and Health

Health Disparities

- African-Americans develop high blood pressure more often, and at an earlier age, than whites and Hispanics do.
- African-Americans are nearly twice as likely as whites to die early from heart disease and stroke.
- American Indians and Alaska Natives die from heart diseases at younger ages than other racial and ethnic groups in the United States. 36% of those who die of heart disease die before age 65.

Source:
Go AS, Mozaffarian D, Roger VL, et al. Heart disease and stroke statistics—2013 update: a report from the American Heart Association. *Circulation*. 2013;127:e6–245.

Morbidity and Mortality Weekly Report (MMWR): Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease — United States, 2001–2010

SS Oh, JB Croft, KJ Greenlund, C Ayala, ZJ Zheng, GA Mensah, WH Giles. Disparities in Premature Deaths from Heart Disease—50 States and the District of Columbia. MMWR 2004;53:121–25. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5306a2.htm

Clinical Quality Measures

ABCS	Number	Measure
A	PQRS 204 NQF 0068	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or other antithrombotic
B	PQRS 317	Preventive Care and Screening: Screening for High Blood Pressure Percentage of patients aged 18 and older who are screened for high blood pressure
B	PQRS 236 NQF 0018	Hypertension: Controlling High Blood Pressure Percentage of patients aged 18 through 85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure (BP) was adequately controlled (<140/90) during the measurement year
C (EHR)	PQRS 316	Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL) Test Performed AND Risk-Stratified Fasting LDL Percentage of patients aged 20 through 79 years whose risk factors have been assessed and a fasting LDL test has been performed AND who had a fasting LDL test performed and whose risk-stratified fasting LDL is at or below the recommended LDL goal

PQRS = CMS Physician Quality Reporting System, NQF = National Quality Forum, EHR = electronic health record

Clinical Quality Measures (cont'd)

ABCS	Number	Measure
C (No EHR)	PQRS #2 NQF #0064	Diabetes Mellitus: Low Density Lipoprotein (LDL-C) Control in Diabetes Mellitus Percentage of patients aged 18 through 75 years with diabetes mellitus who had most recent LDL-C level in control (less than 100 mg/dL)
C (No EHR)	PQRS #241 NQF #0075	PQRS Measure #241 (NQF 0075): Ischemic Vascular Disease (IVD): Complete Lipid Panel and Low Density Lipoprotein (LDL-C) Control Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) who received at least one lipid profile within 12 months and who had most recent LDL-C level in control (less than 100 mg/dL)
S	PQRS 226 NQF 0028	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention Percentage of patients aged 18 years or older who were screened about tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user

PQRS = CMS Physician Quality Reporting System, NQF = National Quality Forum, EHR = electronic health record

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What to Do About Cholesterol? Risk Assessment is the Start , not the End of the Risk Decision in Primary Prevention

Neil J. Stone MD, MACP, FACC
Bonow Professor of Medicine
Feinberg School of Medicine
Northwestern University
Chicago, Il

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Disclosures

No relevant disclosures

I do not accept honoraria from pharmaceutical companies

I served as the chair of the **2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults**

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ACC/AHA Blood Cholesterol Guideline Panel Members

Neil J. Stone, MD, MACP, FAHA, FACC, Chair
Jennifer G. Robinson, MD, MPH, FAHA, Vice Chair
Alice H. Lichtenstein, DSc, FAHA, Vice Chair

Anne C. Goldberg, MD, FACP, FAHA
Conrad B. Blum, MD, FAHA
Robert H. Eckel, MD, FAHA, FACC
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Donald M. Lloyd-Jones, MD, ScM, FACC, FAHA
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National Heart, Lung, and Blood Institute
Glen Bennett, M.P.H.
Denise Simons-Morton, MD, PhD

Stone NJ et al 2013 ACC-AHA Cholesterol Guidelines
JACC Vol. 63, No. 25, 2014

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Synopsis of Recommendations

1. **Encourage adherence to a healthy lifestyle**
2. Statin therapy recommended for adult groups demonstrated to benefit
3. Statins have an acceptable margin of safety when used in properly selected individuals and appropriately monitored
4. Engage in a clinician-patient discussion before initiating statin therapy – especially for primary prevention in patients with lower ASCVD risk

Stone NJ, et al. *Ann Int Med.* 2014

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Guidelines Focus on Healthy Lifestyle

Lifestyle guideline: Healthy lifestyle (dietary patterns and physical activity) improves lipid and blood pressure risk factor levels

Obesity guideline: Lifestyle crucial for weight control

Risk assessment guideline:

- Lifetime risk estimator for those 20-59 years
- Helps identify high lifetime but low 10 year ASCVD risk
- Explicitly **not** used to choose drug therapy
- To enhance clinicians focus on lifestyle and risk factor improvement as low risk individuals by age 50 do best.

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Lifetime Risk Estimator

- For those 20-59 years, it provides lifetime risk estimate
- This is intended to drive discussions of greater adherence to heart-healthy lifestyle

Synopsis of Recommendations

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Stone NJ, et al. *Ann Int Med.* 2014

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Statin Benefit Groups

Secondary Prevention

Diabetes – 40 to 75 yrs
LDL-C 70-189 mg/dl

LDL-C ≥ 190 mg/dL

Rx: Optimal benefit with high intensity statins → lower LDL-C ≥ 50%
Use moderate intensity if age >75 or can't tolerate high intensity

Primary Prevention –

40 to 75 yrs
LDL-C 70-189 mg/dl
ASCVD Risk ≥ 7.5 %

Rx: Moderate intensity
or high intensity statin

Statin Rx not automatic, requires clinician-patient discussion

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Primary Prevention Statin Therapy

- Thresholds for initiating statin therapy derived from 3 exclusively primary prevention RCTs
  - Placebo group- 10 yr event rates:
    JUPITER – 7.6%;
    AFCAPS-TEXCAPS 6.9%
    MEGA 5.1%;

Guideline Panel's Recommendation:

- As a matter of caution, to avoid over-treating, the Panel identified those with risk ≥7.5% as a group in which statins provide benefit.

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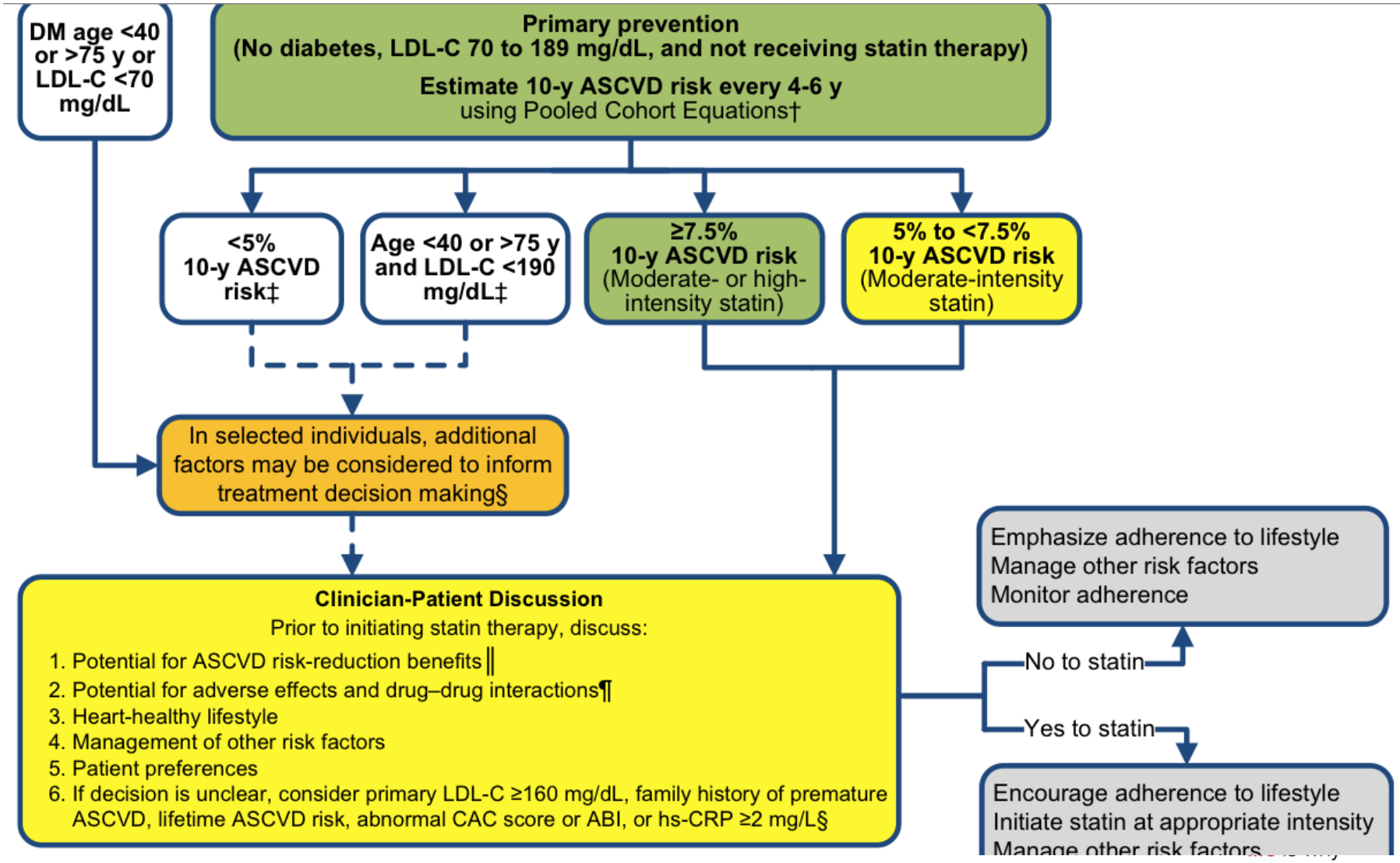
Clinician - Patient Discussion Before Statin Rx Especially Primary Prevention

- ✔ Estimate 10 yr ASCVD Risk Review other risk factors & risk factor control
- ✔ Review potential for benefit from heart-healthy lifestyle
- ✔ Review potential for
  - benefit from statins and potential for adverse effects & drug-drug interactions
- ✔ Patient Preferences

*Factors if risk decision uncertain that improve calibration, discrimination, and reclassification
Family hx premature ASCVD;
hs-CRP≥ 2,
CAC score ≥ 300 or 75th%
ABI < 0.9;

Clinician - Patient Discussion Before Statin Rx in Primary Prevention



The Risk Decision in Young Adults

- 36 yo man with family history of premature CAD & LDL-C 180 mg/dL
  - Too young for the 10 year ASCVD risk estimation
  - Guidelines clearly show →family history of premature CHD and LDL-C of ≥ 160 mg/dL informs the treatment decision re statin
  - Statin therapy would be reasonable after a risk discussion
    - reviewing potential for benefit
    - potential for adverse effects
    - drug-drug interactions &
    - patient preference

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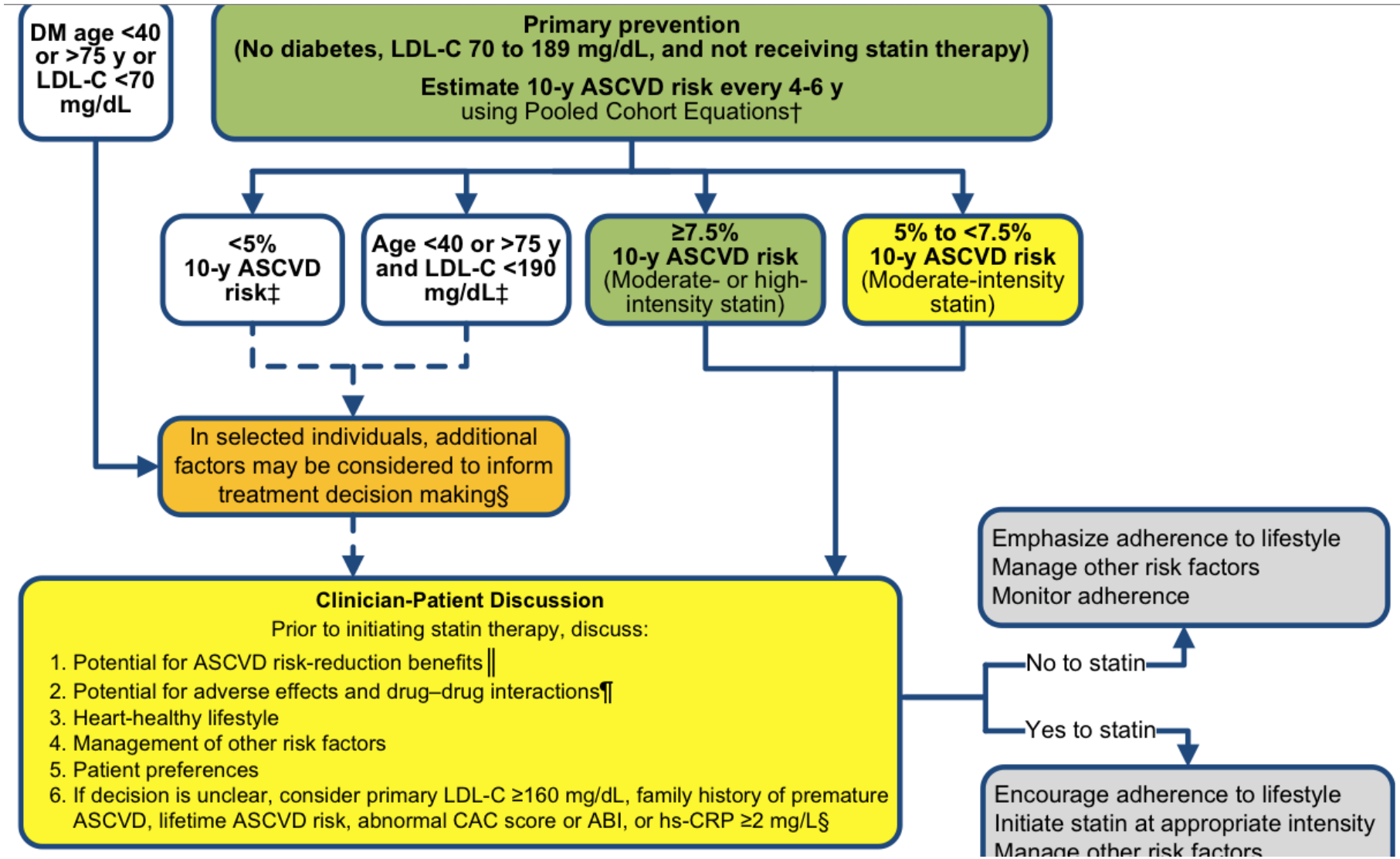
Clinician - Patient Discussion Before Statin Rx in Primary Prevention



The Risk Decision in Older Adults

- 68 yo white man with average risk factors and estimated 10 year ASCVD risk of >7.5%
- Merits a risk discussion to consider adherence to optimal lifestyle, potential for benefit, potential for adverse effects, drug-drug interactions and informed patient preference
- If clinician felt risk decision uncertain, could order: CAC score, hs-CRP or ABI

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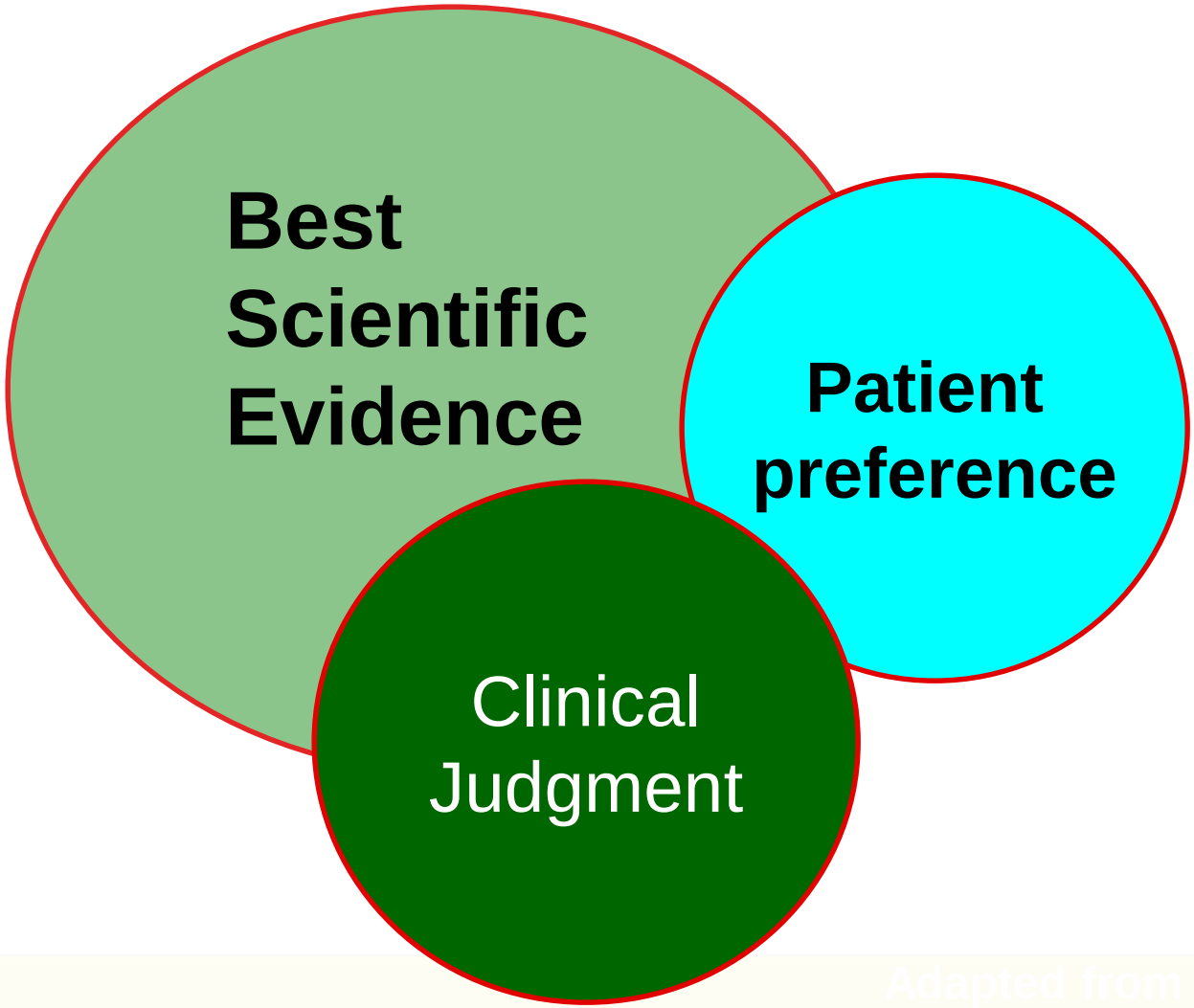
Evidence Based To Inform Risk Decisions



American American

Adapted from Dr. Sanjay Kaul with permission

“Clinician judgment is especially important for several patient groups for which the RCT evidence is insufficient for guiding clinical recommendations.

These patient groups include younger adults (<40 years of age) who have a low estimated 10-year ASCVD risk but a high lifetime ASCVD risk based on single strong factors or multiple risk factors.

Stone NJ et al 2013 Cholesterol Guidelines JACC Vol. 63, No. 25, 2014

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“Other groups include those with serious comorbidities & increased ASCVD risk

(e.g., individuals with HIV or rheumatologic or inflammatory diseases, or who have undergone a solid organ transplantation).

This guideline encourages clinicians to use clinical judgment in these situations, weighing potential benefits, adverse effects, drug–drug interactions, and consider patient preferences.”`

Stone NJ et al 2013 Cholesterol Guidelines JACC Vol. 63, No. 25, 2014

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Synopsis of Recommendations

5. **Use the newly developed pooled cohort equations for estimation 10-year ASCVD risk**

6. Initiate proper intensity of statin therapy

7. Evidence is inadequate to support treatment to specific LDL-C or non-HDL-C goals

8. Regularly monitor patients for adherence to lifestyle and statin therapy

Stone NJ, et al. *Ann Int Med.* 2014

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Original Investigation

Validation of the Atherosclerotic Cardiovascular Disease Pooled Cohort Risk Equations

Paul Muntner, PhD; Lisandro D. Colantonio, MD; Mary Cushman, MD; David C. Goff Jr, MD, PhD; George Howard, DrPh; Virginia J. Howard, PhD; Brett Kissela, MD, MS; Emily B. Levitan, ScD; Donald M. Lloyd-Jones, MD, ScM; Monika M. Safford, MD

IMPORTANCE The American College of Cardiology/American Heart Ass
Pooled Cohort risk equations were developed to estimate atheroscler
disease (CVD) risk and guide statin initiation.

OBJECTIVE To assess calibration and discrimination of the Pooled Coh
contemporary US population.

DESIGN, SETTING, AND PARTICIPANTS Adults aged 45 to 79 years enrol
Geographic and Racial Differences in Stroke (REGARDS) study betwee
October 2007 and followed up through December 2010. We studied p
atherosclerotic CVD risk may trigger a discussion of statin initiation (th
atherosclerotic CVD or diabetes, low-density lipoprotein cholesterol le
189 mg/dL, and not taking statins; n = 10 997).

MAIN OUTCOMES AND MEASURES Predicted risk and observed adjudic
CVD incidence (nonfatal myocardial infarction, coronary heart disease
or fatal stroke) at 5 years because REGARDS participants have not bee
years. Additional analyses, limited to Medicare beneficiaries (n = 3333
atherosclerotic CVD events identified in Medicare claims data.

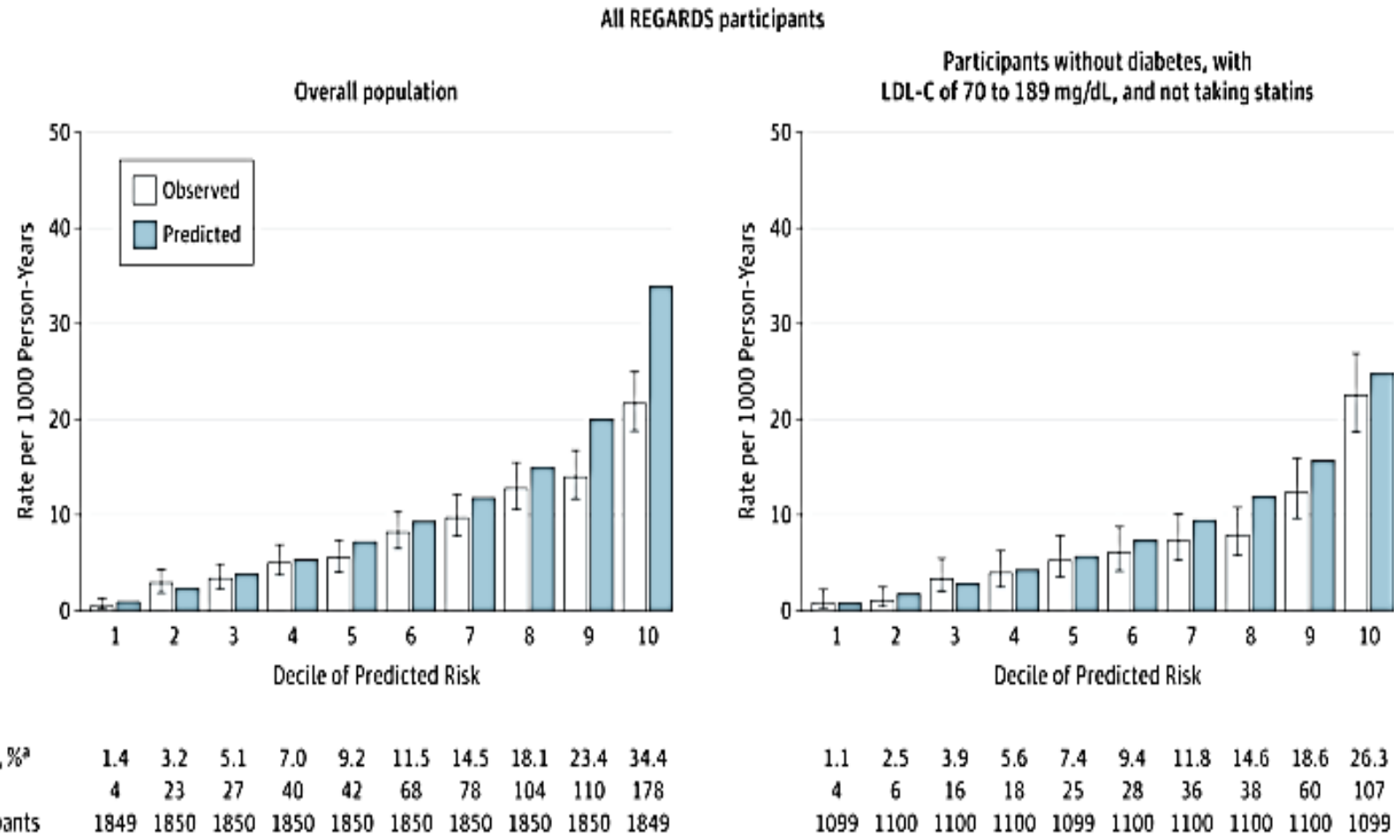
RESULTS There were 338 adjudicated events (192 CHD events, 146 str
and predicted 5-year atherosclerotic CVD incidence per 1000 person-
with a 10-year predicted atherosclerotic CVD risk of less than 5% was 1.9 (95% CI, 1.3-2.7) and 1.9, respectively, risk of 5% to less than 7.5% was 4.8 (95% CI, 3.4-6.7) and 4.8, risk of 7.5% to less than 10% was 6.1 (95% CI, 4.4-8.6) and 6.9, and risk of 10% or greater was 12.0 (95% CI, 10.6-13.6) and 15.1 (Hosmer-Lemeshow χ^2 = 19.9, P = .01). The C index was 0.72 (95% CI,

In this cohort of US adults for whom statin initiation may be considered based on the ACC/AHA Pooled Cohort risk equations

- **observed and predicted 5-year atherosclerotic CVD risks were similar**
- **indicating that these risk equations were well calibrated in the population for which they were designed to be used,**
- **demonstrated moderate to good discrimination.**

Muntner et al. JAMA March 2014

Pooled Cohort Equations: External Validation in ReGARDS Population



	Overall population									
Mean predicted risk, %[a]	1.4	3.2	5.1	7.0	9.2	11.5	14.5	18.1	23.4	34.4
No. of events	4	23	27	40	42	68	78	104	110	178
No. of participants	1849	1850	1850	1850	1850	1850	1850	1850	1850	1849

	Participants without diabetes, with LDL-C of 70 to 189 mg/dL, and not taking statins									
Mean predicted risk, %[a]	1.1	2.5	3.9	5.6	7.4	9.4	11.8	14.6	18.6	26.3
No. of events	4	6	16	18	25	28	36	38	60	107
No. of participants	1099	1100	1100	1100	1099	1100	1100	1100	1100	1099

Muntner P, et al. JAMA 2014; 311:1406-1415.

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For Some Groups Pooled Cohort Equations Overestimate or Underestimate ASCVD Risk

1. Overestimation in high socioeconomic status (SES) healthy volunteers for clinical trials

   Claim based on analyses of Women's Health Study, Physician's Health Study, Women's Health Initiative Observational Study
   - **Risk factor levels were self-reported in these studies**
   - **The participants in these studies (esp. PHS) were not broadly representative of the US population**

2. Underestimation in South Asians

   Both of these are examples where the risk discussion allows the needed calibration

Ridker PM and Cook NR. Lancet 2013; 382:1762-1765; Cook, Rider, JAMA Internal Medicine October 2014
**Hlatky MA et al. Circulation: Cardiovsc Qual Outcomes. 2014; 7:157-162

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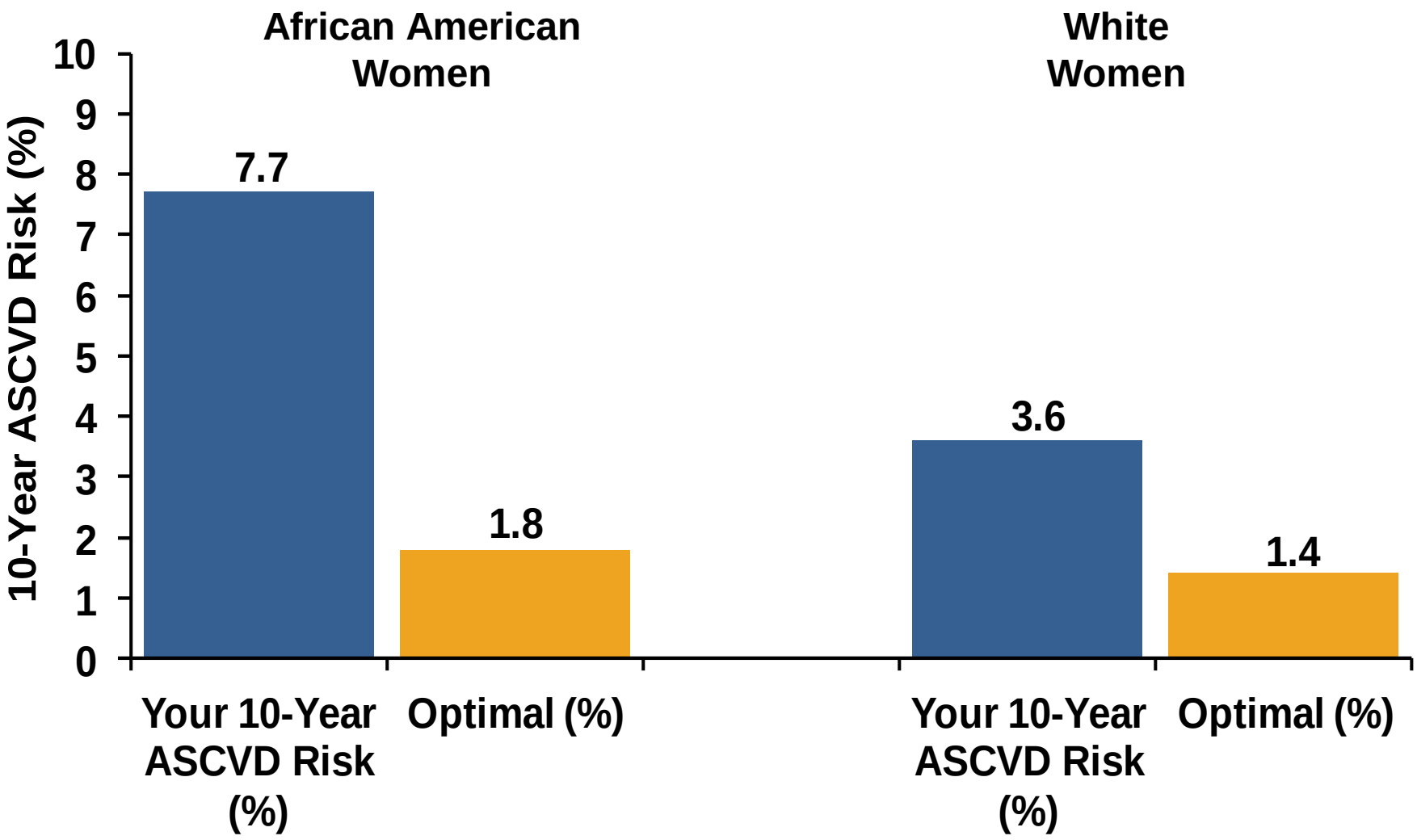
ASCVD Risk Calculator Pooled Cohort Equations

Risk Factor	Units	Value	Acceptable range of values	Optimal values
Sex	M or F	**F**	M or F	
Age	years	**55**	20-79	
Race	AA or WH	**AA**	AA or WH	
Total Cholesterol	mg/dL	**210**	130-320	170
HDL-Cholesterol	mg/dL	**56**	20-100	50
Systolic Blood Pressure	mm Hg	**145**	90-200	110
Treatment for High Blood Pressure	Y or N	**Y**	Y or N	N
Diabetes	Y or N	**N**	Y or N	N
Smoker	Y or N	**N**	Y or N	N

ASCVD Risk Calculator
55 yo AA and White Women



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Accuracy of Statin Assignment Using the 2013 AHA/ACC Cholesterol Guideline Versus the 2001 NCEP ATP III Guideline

Correlation With Atherosclerotic Plaque Imaging

Kevin M. Johnson, MD,* David A. Dowe, MD†

ABSTRACT

BACKGROUND Accurate assignment of statin therapy is a major public health issue.

OBJECTIVES The American Heart Association and the American College of Cardiology released a new guideline on the assessment of cardiovascular risk (GACR) to replace the 2001 National Cholesterol Education Program (NCEP) Adult Treatment Panel III recommendations. The aim of this study was to determine which method more accurately assigns statins to patients with features of coronary imaging known to have predictive value for cardiovascular events and whether more patients would be assigned to statins under the new method.

METHODS The burden of coronary atherosclerosis on computed tomography angiography was measured in several ways on the basis of a 16-segment model. Whether to assign a given patient to statin therapy was compared between the NCEP and GACR guidelines.

Current Guidelines Identify Plaque Burden More Accurately

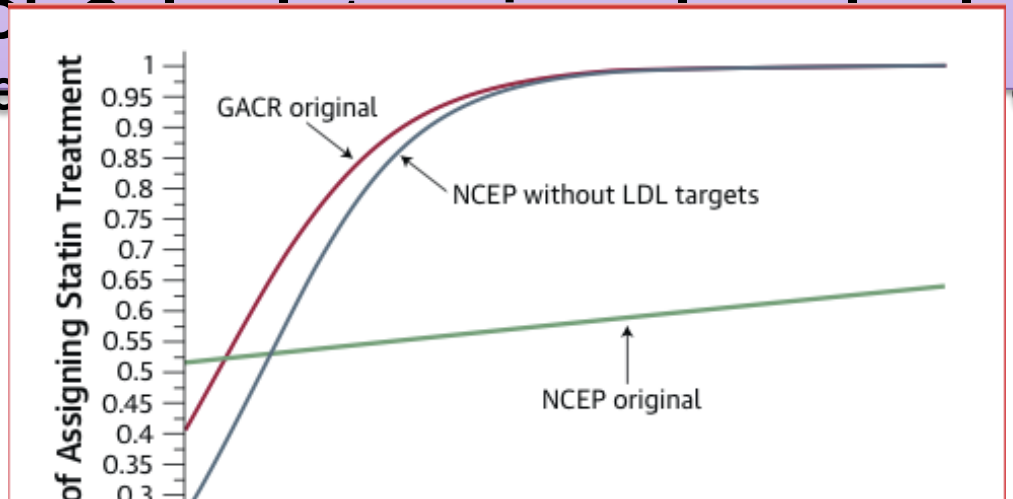
Population: 3,076 subjects; 65.3% men mean age 55; women 59; >90% white
At time of imaging 44% not on statins

Probability of statin Rx rose sharply with increasing plaque burden with Guideline on Risk Assessment estimation of risk (GACR)

The GACR assigned fewer patients with no plaque to statins & more patients with heavy plaque to statins.

The correlation of serum LD[illegible] is essentially zero. Targets de[illegible] of patients

to statin therapy.



ORIGINAL ARTICLE

Application of New Cholesterol Guidelines to a Population-Based Sample

Michael J. Pencina, Ph.D
Ralph B. D'Agostino, Ph.D.,
Allan D. Sniderman, M

BACKGROUND

The 2013 guidelines of the Ameri
Association (ACC–AHA) for the t
statin therapy for the prevention

METHODS

Using data from the National Hea
2010, we estimated the number, a
who would be recommended (i.e.,
guidelines, as compared with th
(ATP III) of the National Cholester
to a population of 115.4 million

RESULTS

As compared with the ATP-III g
number of U.S. adults who are
therapy from 43.2 million (37.5%
numbers (10.4 million of 12.8 million) would occur among adults without cardio-

More adults eligible for statin treatment under the new ACC/AHA guideline:

Statins: **43 million (37.5%) → 56 million (48.6%)**

Those who were reclassified upward as contrasted to tho
reclassified downward:

1) older
2) more men
3) higher systolic blood pressure,
4) had a significantly lower level of LDL-C
5) higher rate of obesity.

Pencina et al NEJM 2014

This article was published on March 19, 2014, at NEJM.org.

New Guidelines Efficiently Choose Additional Individuals to Get Statin Rx (Dallas Heart Study)

Table. Additional Statin Eligibility and ASCVD Event Rates Among Newly Statin Eligible Individuals

Outcome	Additional Statin Eligibility*	Event Rate Among Newly Statin Eligible	NNT Among Newly Statin Eligible†
Primary analysis			
ASCVD	4.8%	15.8%	14–21
CHD	4.8%	11.7%	19–29
ATPIII statin eligibility determined by optional cholesterol goals			
ASCVD	−2.8%	15.7%	14–21
CHD	−2.8%	12.4%	18–27
Restricting to individuals aged ≥40 years			
ASCVD	9.0%	15.8%	14–21
CHD	9.0%	11.6%	19–29

Paixao ARM et al. *Circ Cardiovasc Qual Outcomes.* 2014;7:

Risk of New Diagnosis of DM with statins depends on

- **Statin intensity (ACC-AHA Guidelines 2013)**
  - 1 in 1000 cases for moderate
  - 3 in 1000 cases for high intensity

- **Number of DM Risk factors**
  - 4 diabetes risk factors: **BMI ≥ 30; FBS ≥ 100; A1c ≥ 6.0%, Metabolic risk factors (Ridker P et al**. *Lancet* 2012; 380: 565–71)
  - **New onset DM (NODM) risk** -Atorvastatin 80 mg/d v less intense statin Rx
    - No increase if 0 to 1 NOD risk factors
    - 24%, increase if 2 to 4 NOD risk factors.
    - **The number of CV events was significantly reduced with atorvastatin 80 mg in both NOD risk groups. (Waters et al J Am Coll Cardiol 2013)**

- **One year change in body weight** as in TNT trial (Ong K-L et al. (Am J Cardiol 2014;113:1593e1598)

Statins accelerated the average time to diagnosis of diabetes by 5·4 weeks as those on placebo

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Guidelines as easy as ABC….

Always encourage adherence to lifestyle (even if receives a statin)

Bring practice close to the RCT evidence:
No arbitrary fixed LDL-C or non HDL-C goals
Data supports **appropriate intensity of statins** for higher ASCVD risk groups in whom statins shown to benefit:
Secondary prevention, Primary LDL-C≥190 mg/dl; Diabetes 40-75 yrs

Choose Risk Estimator to estimate lifetime and 10 year risk with ASCVD risk estimator in primary prevention. It provides useful decision support. Not for those on treatment already.

Discuss attention to risk factor control, lifestyle, potential for benefit as well as adverse effects, drug-drug interactions and patient preference in a clinician-patient risk discussion. This precedes statin Rx in primary prevention. ***Statin Rx not automatic!!***

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Guidelines as easy as ABC….

Evaluate additional factors that can inform the risk discussion. Factors chosen if they improved discrimination, calibration, & reclassification of the risk assessment (not arbitrary)

1. **Family history of premature ASCVD**
2. **CAC score ≥ 300 or ≥75th%**
3. **hs-CRP ≥2.0 mg/L**
4. **ABI<0.9**
5. **May use a primary elevation of LDL-C ≥ 160 mg/dl**
6. **Use lifetime risk estimation in those 20-59 to enhance discussion of need for more optimal lifestyle to improve entire risk profile.**

Follow-up needed to evaluate adherence to therapy, adequacy of treatment effect achieved with follow-up lipids/safety checks

Give consideration to "proven" non-statins in "high risk" groups→
--LDL-C ≥ 190 mg/dl secondary prevention, high risk DM

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Relevant AHA Cholesterol Resources for Patients and Providers

2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. E-Published on November 12, 2013, available at: http://circ.ahajournals.org/lookup/doi/10.1161/01.cir.0000437738.63853.7a

Understanding and Managing Cholesterol

– Interactive guide including quizzes, videos and more to help patients manage their cholesterol.

Downloadable Toolkit for Providers:

- **Pocket Guide** - Information about guidelines for treating patients with high cholesterol
- **Referral Pad** - Instructs patients on how to sign up for Heart360
- **Waiting Room Poster** - Encourages enrollment in Heart360
- **Quick Start Guide** - Shows you how to enroll in Heart360

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Questions & Answers

Laura King Hahn, American Heart Association
Neil J. Stone, MD, Northwestern University Feinberg School of Medicine

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Thank You!

For more information, please visit the CDC's Million Hearts® website at:
millionhearts.hhs.gov
or
the AHA's Million Hearts® webpage at:
http://www.heart.org/HEARTORG/Advocate/American-Heart-Association-Million-Hearts_UCM_463392_Article.jsp