#### The Clinician's Conundrum

# The First Line of Defense Against ASCVD Events: How are Clinicians Doing In the Treatment of High-risk Patients?

Salim S. Virani, MD, PhD
Michael E DeBakey VA Medical Center
Section of Cardiovascular Research, Baylor College of
Medicine
Houston, Texas





#### **Disclosures**

- Research support: Department of Veterans
   Affairs Health Services Research &
   Development, American Diabetes Association,
   American Heart Association, Baylor College of
   Medicine Global Initiatives
- Member, Steering Committee, Patient and Provider Assessment of Lipid Management (PALM) Registry at the Duke Clinical Research Institute (DCRI) [No financial remuneration]
- Honorarium: American College of Cardiology (Associate Editor for Innovations, ACC.org)

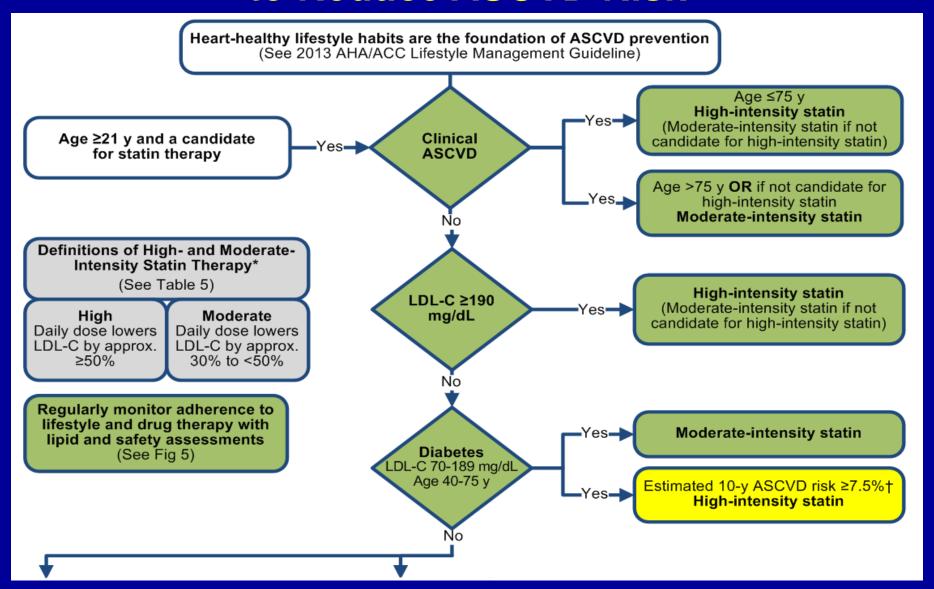
#### **Discussion Points**

 Define high-risk patients as per the 2013 ACC/AHA cholesterol guideline.

 How are we doing in terms of cholesterol treatment of these high-risk patients.

 Impact of the 2013 ACC/AHA guideline on the treatment of these high-risk patients.

# Summary of Statin Initiation Recommendations to Reduce ASCVD Risk



### **Intensity of Statin Therapy**

Table 5. High- Moderate- and Low-Intensity Statin Therapy (Used in the RCTs reviewed by the Expert Panel)\*

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy	
Daily dose lowers LDL–C on average, by approximately ≥50%	Daily dose lowers LDL-C on average, by approximately 30% to <50%	Daily dose lowers LDL–C on average, by <30%	
Atorvastatin (40†)–80 mg Rosuvastatin 20 (40) mg	Atorvastatin 10 (20) mg Rosuvastatin (5) 10 mg Simvastatin 20–40 mg‡ Pravastatin 40 (80) mg Lovastatin 40 mg Fluvastatin XL 80 mg Fluvastatin 40 mg bid Pitavastatin 2–4 mg	Simvastatin 10 mg Pravastatin 10–20 mg Lovastatin 20 mg Fluvastatin 20–40 mg Pitavastatin 1 mg	

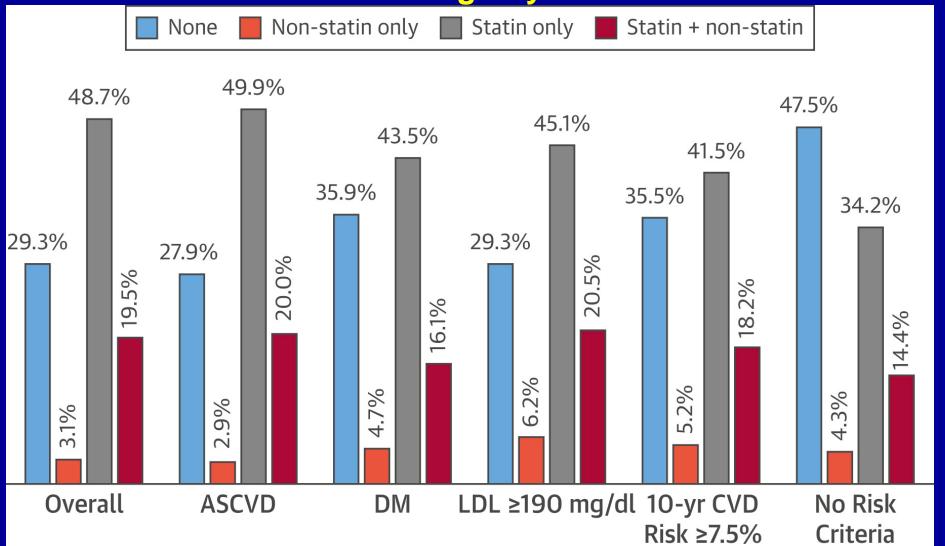
<sup>\*</sup>Individual responses to statin therapy varied in the RCTs and should be expected to vary in clinical practice. There might be a biologic basis for a less-than-average response.

‡Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis.

Stone NJ et al. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2935-59.

<sup>†</sup>Evidence from 1 RCT only: down-titration if unable to tolerate atorvastatin 80 mg in IDEAL (Pedersen et al).

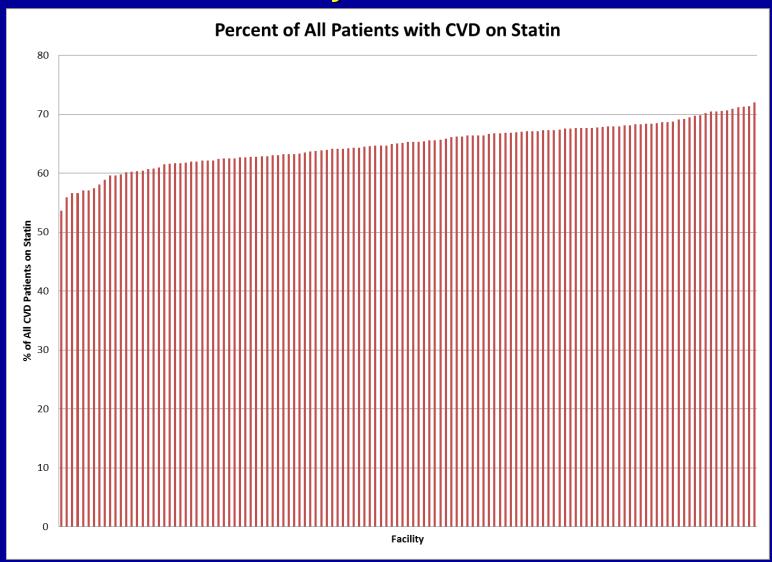
Implications of the 2013 ACC/AHA cholesterol guidelines for adults in contemporary cardiovascular practice: insights from the NCDR PINNACLE registry



### Statin and high intensity statin use in a National Cohort of CVD patients receiving care in the VA system

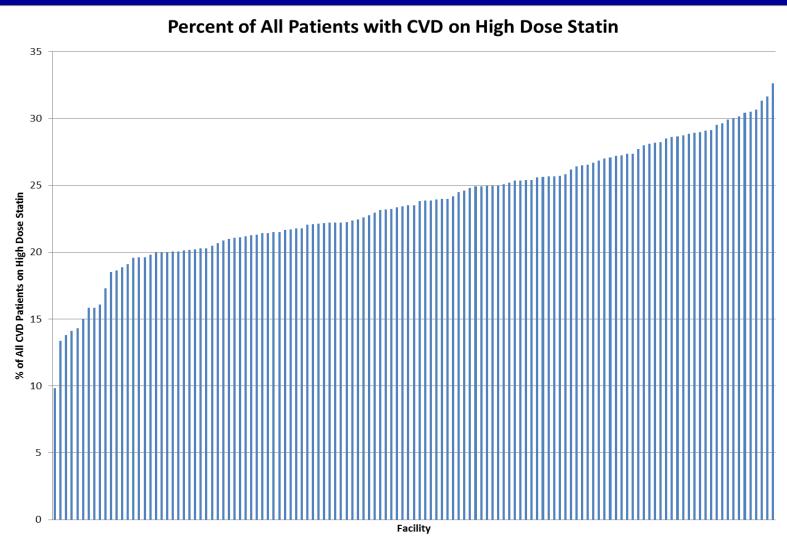
Medication use or lipid parameter	Female CVD patients n = 13,371	Male CVD patients n = 959161	р
Any statin use, n (%)	7696 (57.6)	621309 (64.8)	<.0001
High dose statin use, n (%)	2828 (21.1)	226609 (23.6)	<.0001
Total cholesterol (mg/dL), mean/SD	178.6/45.2	153.9/37.2	<.0001
LDL-C (mg/dL), mean/SD	99.2/38	85/30.4	<.0001
HDL-C (mg/dL), mean/SD	51.3/16.8	42/12.4	<.0001
Triglycerides (mg/dL), mean/SD	153.5/123	147.5/106.7	<.0001
Non-HDL-C† (mg/dL), mean/SD	128/44.2	112.5/35.8	<.001

### Facility-level variation in statin use among CVD patients in the VA Health Care System

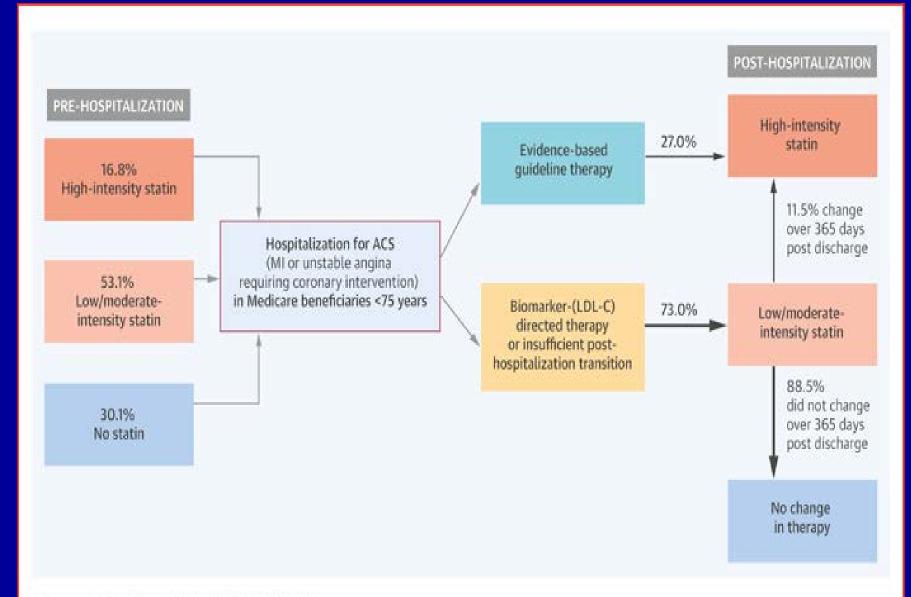


Median= 65.3% (IQR = 5.1%)

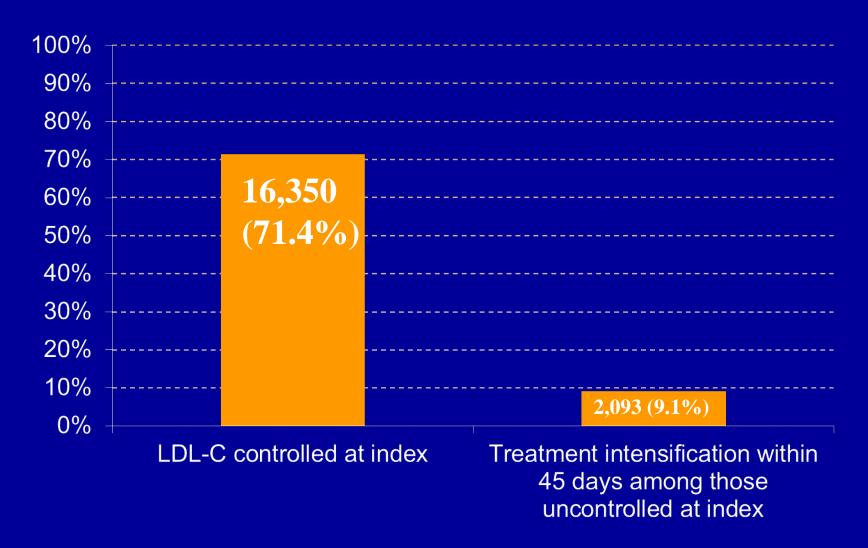
### Facility-level variation in high-dose statin use among CVD patients in the VA Health Care System



Median= 23.5% (IQR = 5.6%)



## Clinical inertia in Lipid lowering treatment intensification among patients with CVD (n= 22,888)

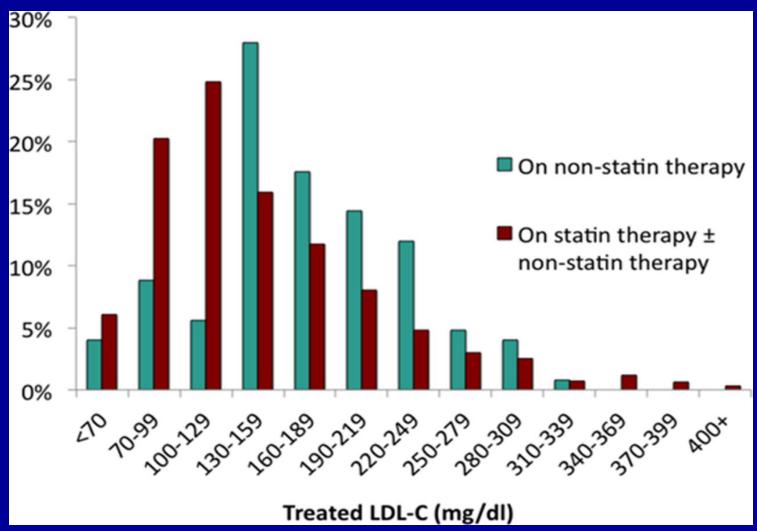


Virani SS et al. *Am Heart J.* 2011;162(4):725-732

# Treatment Gaps in Adults With Heterozygous Familial Hypercholesterolemia in the United States: Data From the CASCADE-FH Registry

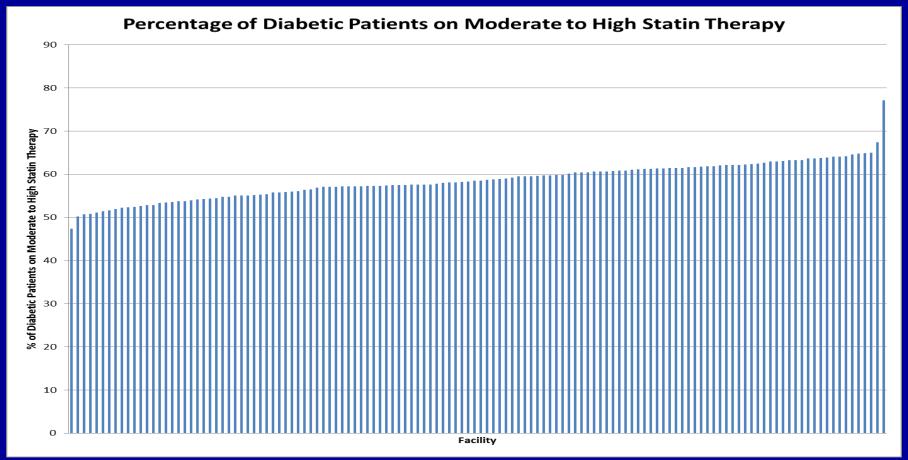
FH history				
Age at FH diagnosis, y, median (IQR), n=1232	47 (31–59)			
Age at initiation of LDL-lowering therapy, y, median (IQR), $n=677$	39 (25–50)			
Family history of premature MI, %, n=938	45.0			
LDL-C, mg/dL, median (IQR)				
Untreated, n=888	239 (211–294)			
Treated, n=1084	134 (100–183)		Overall Cohort (n. 1205)	Ctatin Treated (n. 000)*
Entry, mg/dL, n=1278	141 (103–197)		Overall Cohort (n=1295)	Statin-Treated (n=969)*
Cardiovascular risk factors		Statin intensity†		
Number of additional modifiable cardiovascular risk factors, %*		High	544 (42.0%)	544 (56.1%)
0	38.8	Low/moderate		105 (10 00()
1	37.8		425 (32.8%)	425 (43.9%)
2	16.1	No statin	326 (25.2%)	
3	6.6	THE CHAIN	020 (201210)	
4	0.8	Linid lawaring madications		
Diabetes mellitus, %, n=1280	13.0	Lipid-lowering medications		
Current smoker, %, n=1272	6.9	0	196 (15.1%)	0 (0.0%)
Hypertension, %, n=1283	42.8		F45 (00 00)	100 (44 000)
Low HDLC ( $<$ 40 mg/dL in men, $<$ 50 mg/dL in women), %, n=1285	31.0	1	515 (39.8%)	428 (44.2%)
Obesity (body mass index >30 kg/m²), %, n=1223	31.5	2	389 (30.0%)	353 (36.4%)
Body mass index, kg/m², median (IQR), n=1223	27.3 (24.2–31.0)	3+	195 (15.1%)	188 (19.4%)
Cardiovascular disease			, ,	, ,
ASCVD, %, n=1273†	37.9	Lipoprotein apheresis	77 (6.1%)	37 (3.9%)
Age at onset, y, median (IQR)	52 (42–61)			
CHD, overall cohort, %	35.9			

# Distribution of treated LDL-C levels by treatment status among adults with heterozygous FH on LDL-C lowering therapy (n=1084)



### Statin Use and its Facility-Level Variation in a National Sample of Diabetic Patients (n = 911,444)

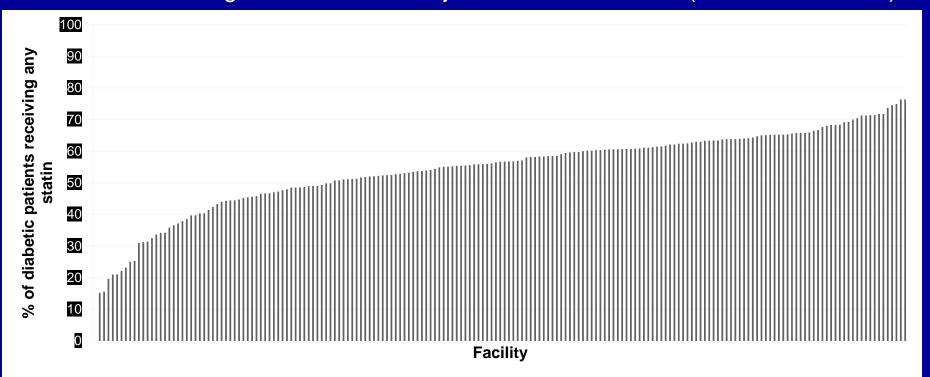
- Statin and at least a moderate intensity statin use among diabetic patients was 68% and 58%, respectively.
- MRR 1.19 (1.116-1.21) for statins and 1.29 (1.25-1.33) for moderate-high intensity statin therapy



Pokharel Y et al. Clin Cardiol. 2016 Apr;39(4):185-91.

# Percentage of 40-75 years old patients with diabetes and without CVD receiving statin therapy in cardiology practices participating in the ACC NCDR® PINNACLE registry

- 215,193 patients with diabetes aged 40-75 years without documented CVD receiving care in cardiology practice all over U.S.
- Statin use documented in only 61.6% of patients.
- Median practice statin prescription rate was 62.3% (IQR: 55.7%-68.1%), with no noticeable change over time. The adjusted MRR\* was 1.56 (95% CI: 1.51-1.60)

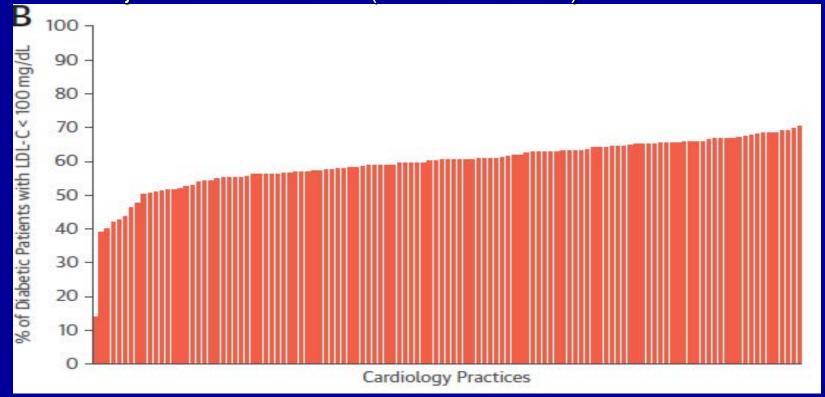


<sup>\*</sup>Adjusted for patient's age, gender, race, hypertension, dyslipidemia, tobacco use, insurance, provider type and non-statin lipid lowering therapy use

# Percentage of 40-75 years old patients with diabetes and without CVD receiving statin therapy in cardiology practices participating in the ACC PINNACLE registry

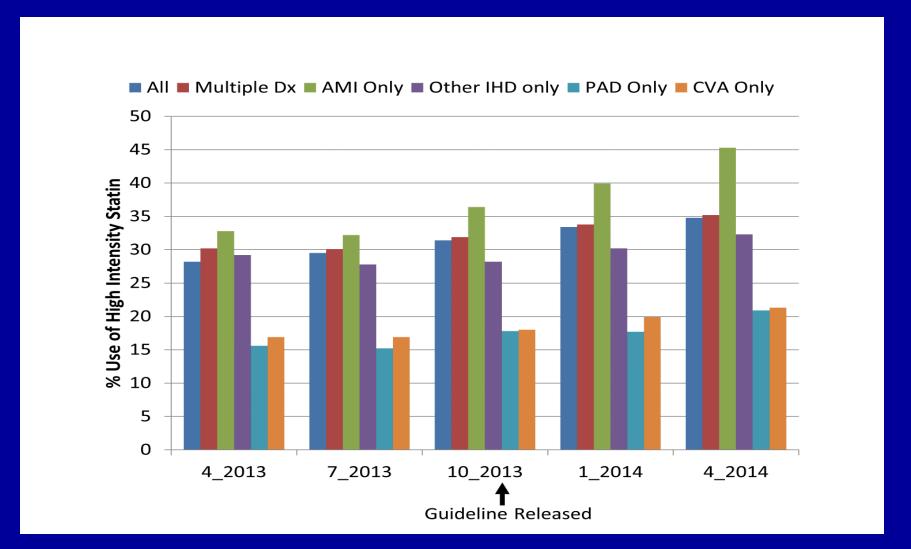
- 215,193 patients with diabetes without documented CVD receiving care in cardiology practice all over U.S.
- LDL-C <100 mg/dL documented in 57.7% of the patients.

• The adjusted MRR\* was 1.47 (95% CI: 1.42-1.50)

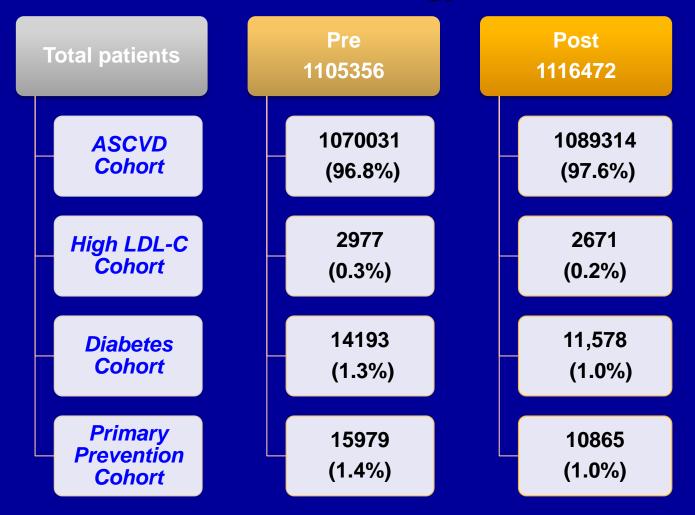


<sup>\*</sup>Adjusted for patient's age, gender, race, hypertension, dyslipidemia, tobacco use, insurance, provider type and non-statin lipid lowering therapy use

#### Use of High-Intensity Statins for Patients with ASCVD in the Veterans Affairs Health System: Practice Impact of the New Cholesterol Guidelines

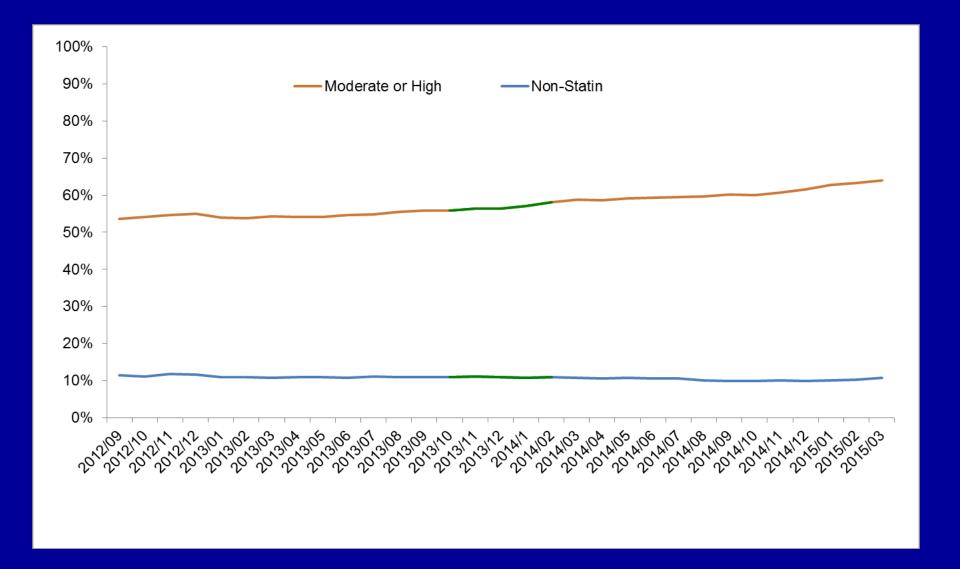


# Adoption of the 2013 American College of Cardiology/American Heart Association Cholesterol Management Guideline in Cardiology Practices Nationwide



### Impact of the 2013 ACC/AHA Cholesterol Guidelines on Cholesterol Management in Cardiology Practices

Cohorts	P slope	Pre-guideline Statin/ Moderate to High Intensity Statin Use (%)	Post-guideline Statin/ Moderate to High Intensity Statin Use (%)
ASCVD	<0.001	71.4/62.7	76.2/67
High LDL-C	0.342	59.2/50.6	60.9/52.3
Diabetes	0.305	63.8/52.4	67/55.2
Primary prevention	0.620	51.2/41.9	55.1/46.9



#### **Conclusions**

- Treatment gaps persist in evidence-based use of statins and especially high-intensity statin therapy in high-risk patients.
- Publication of the 2013 ACC/AHA guideline had a modest effect on evidence based statin therapy use in most high-risk patients.
- There is a need to understand provider, patient and system-level gaps to identify and intervene on the drivers of low evidencebased use of statin therapy.

### Acknowledgements

- Laura A. Petersen, MD, MPH
- Christie M. Ballantyne, MD
- Julia Akeroyd, MPH
- Yashashwi Pokharel, MD
- Mark Kuebeler, MSC
- Fatima Rodriguez, MD
- ACC NCDR® PINNACLE Registry