Statin therapy guidelines 2017

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Table 5. Odds Ratios (ORs) for Clinical Outcomes of Statin Treatment vs Placebo by Type of Study*

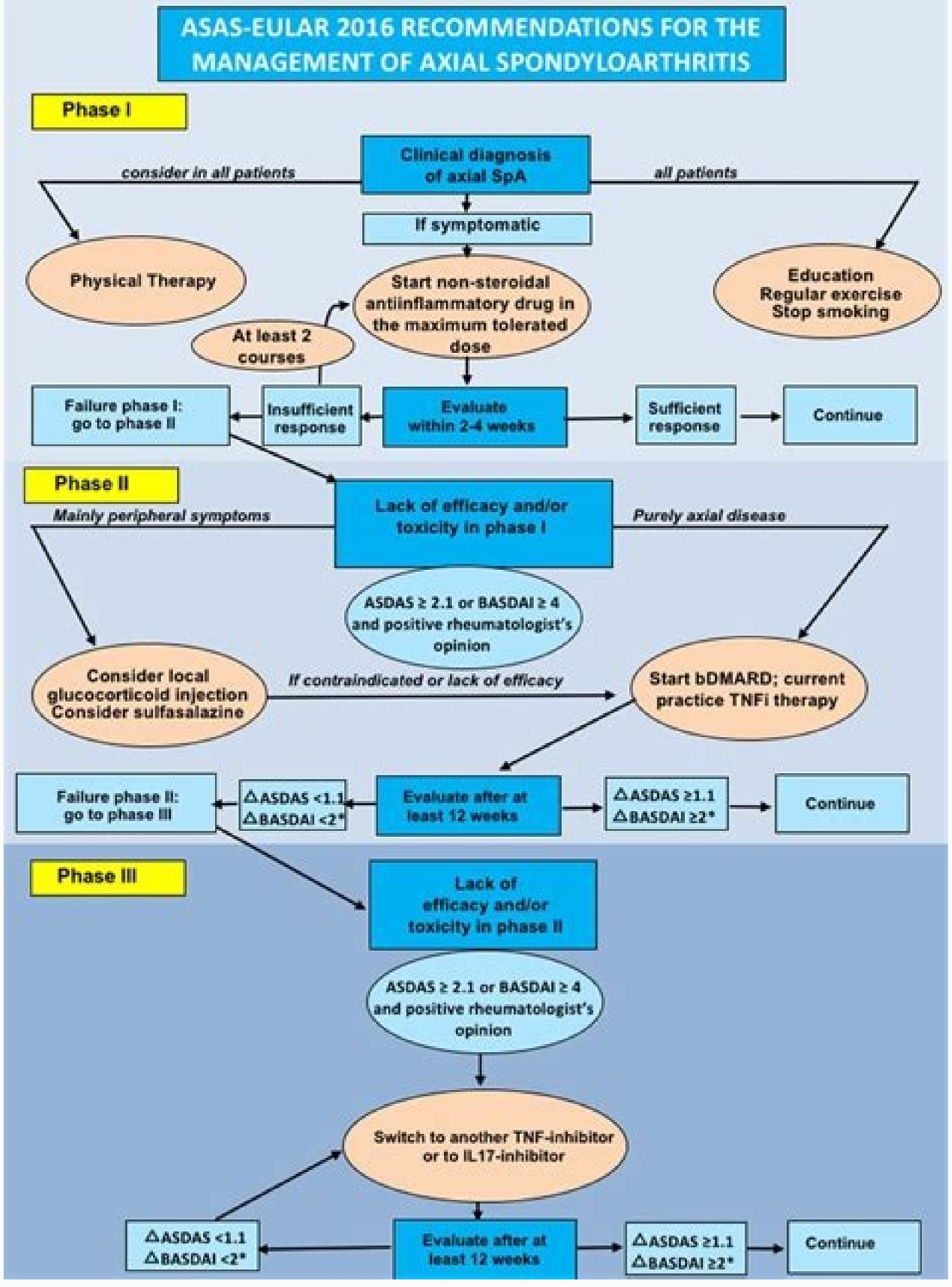
	All Studies			Mixed Population Studies		Secondary Prevention Studies		Regression Studies	
Clinical Outcome	No.	OR (95% CI)	NNT	No.	OR (95% CI)	No.	OR (95% CI)	No.	OR (95% CI)
All-cause mortality	14	0.76 (0.67-0.86)	67	4	0.77 (0.59-0.99)	2	0.79 (0.60-1.04)	8	0.52 (0.32-0.85)
Fatal myocardial infarction	14	0.61 (0.48-0.78)	166	4	0.71 (0.47-1.07)	2	0.53 (0.38-0.74)	8	0.72 (0.31-1.66)
Fatal stroke	10	0.77 (0.57-1.04)	500	4	1.26 (0.44-3.66)	2	0.80 (0.50-1.27)	4	0.43 (0.08-2.39)
Nonfatal myocardial infarction	13	0.66 (0.57-0.77)	43	3	0.58 (0.30-1.14)	2	0.66 (0.50-0.87)	8	0.69 (0.44-1.09)
Nonfatal stroke	7	0.69 (0.54-0.88)	143	3	0.82 (0.54-1.24)	1	0.63 (0.46-0.86)	3	0.52 (0.20-1.38)
Angina	12	0.70 (0.65-0.76)	24	3	0.45 (0.13-1.50)	2	0.71 (0.65-0.78)	7	0.66 (0.53-0.83)
Withdrawals	11	0.80 (0.61-1.04)†	NA	3	0.95 (0.85-1.05)	2	0.56 (0.28-1.08)†	6	0.90 (0.62-1.31)†

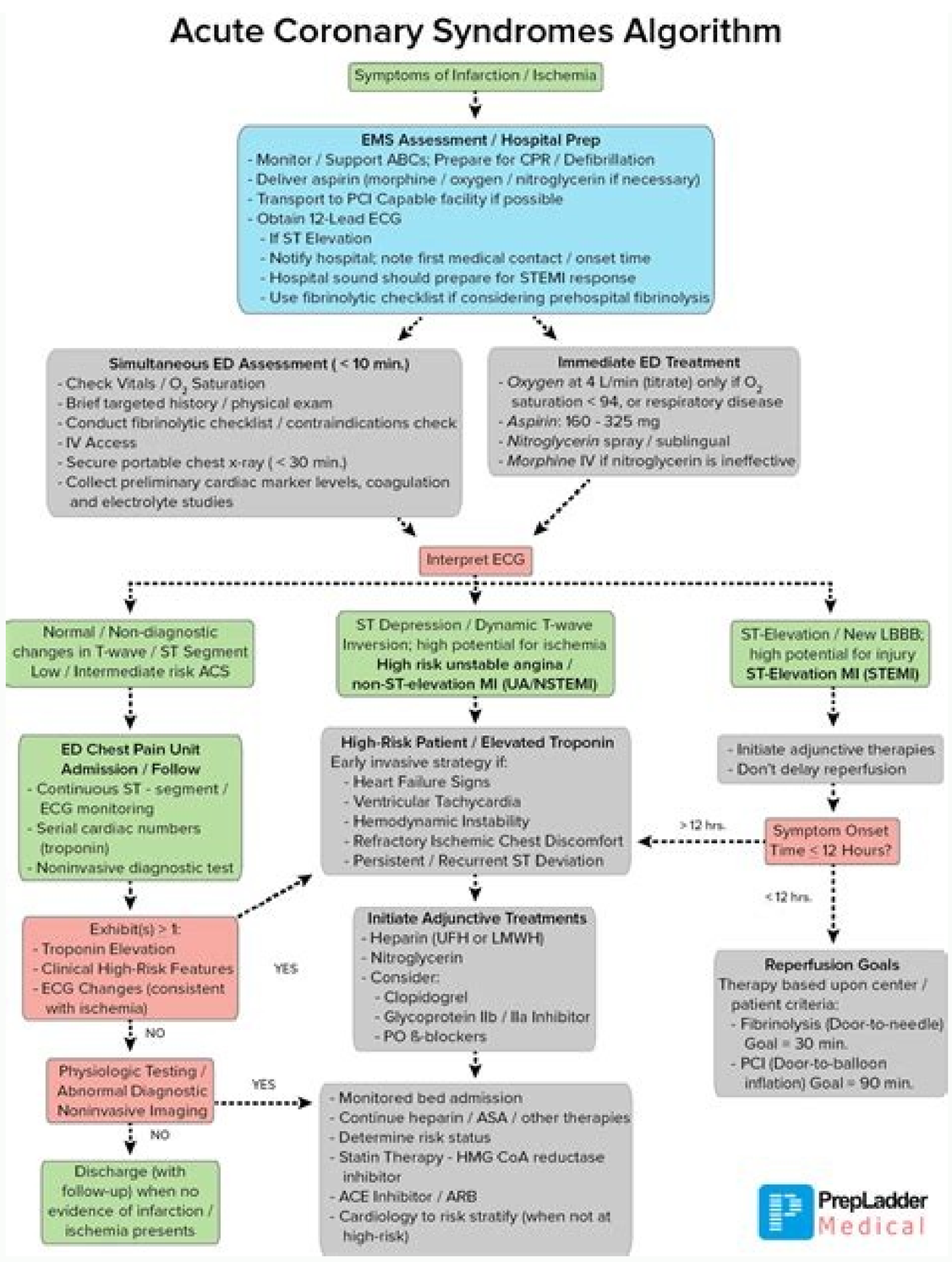
*Includes studies with intent-to-treat denominators. ORs are derived from random-effects model meta-analysis. CI indicates confidence interval; NNT, number needed to treat; and NA, not applicable.
†Heterogeneity test result was significant.

Table 4. Lipid Profile Changes From Baseline in Available Studies

			Active Group Mean Difference From Baseline				Placebo Group Mean Difference From Baseline			
Study	Statin Used	Sex	TC	LDL	HDL	Trg	TC	LDL	HDL	Trg
CARE[32]	Pravastatin, 40 mg/d	M	−19	−28	+5	−14	NA	NA	NA	NA
		F	−20	−28	+4	−13				
CCAIT[37,38]	Lovastatin, 20 mg/d[a]	M	−20	−28	+7.7	−8	−1.2	−1.4	+2.9	+4.4
		F	−24	−32	+5.4	−8.4	−2.4	−2.9	+3.4	+1.5
SPARCL[7-13]	Atorvastatin, 80 mg/d	M	−39	−26.7	+7	−11.2	−4.4	−2.6	+3.2	+5.6
		F	−35.3	−23.2	+4.6	−10.5	−9.1	−5.7	+4.2	+3.2
4S[35,39,47]	Simvastatin, 20 mg/d[a]	M	−25.1	−34	+6.9	−15.8	NA	NA	NA	NA
		F	−26.4	−37.4	+7.2	−15.5				
Average	All	M	−25.8	−29.2	+6.7	−11.9	−2.8	−2	+3.1	+5
		F	−26.4	−30.2	+5.3	−11.9	−5.8	−4.3	+3.8	+2.4

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein; NA, not available; TC, total cholesterol; Trg, triglycerides.
[a]Dose doubled if LDL levels not at goal.





SURVIVING SEPSIS CAMPAIGN RECOMMENDATION HIGHLIGHTS		
	2012	2016
SEPSIS DEFINITION	Systemic manifestation of infection + suspected infection Severe sepsis: sepsis + organ dysfunction	Life threatening organ dysfunction caused by dysregulated response to infection No severe sepsis category
INITIAL RESUSCITATION	at least 30 cc/kg in first 3 hours Crystalloid fluid (no recommendations on 0.9% NaCl vs balanced solution) Albumin if patients require "substantial" fluids (weak)	
	Protocolized care including CVP ScVO2 Normalize lactate	Use dynamic resuscitation markers (passive leg raise) Target MAP of 65mmHg Reassess hemodynamic status to guide resuscitation Normalize lactate
VASOPRESSORS	target MAP of 65 mmHg 1. Norepinephrine 2. Epinephrine if not at target MAP OR vasopressin to reduce norepinephrine requirement 3. Avoid dopamine in most patinets	
STEROIDS	Only indicated for patients with septic shock refractory to adequate fluids and vasopressors	
ANTIBIOTICS	One or more antibiotics active against presumed pathogen Combination therapy (double coverage) for neutropenic patients and pseudomonas	Initial broad spectrum antibiotics (ex: vancomycin + piperacillin-tazobactam) Against combined therapy (i.e. do not double cover pseudomonas) May use procalcitonin to guide de-escalation
SOURCE CONTROL	Achieve within 12 hours, if feasible	Achieve as soon as medically and logically feasible
VENTILATOR	6 cc/kg tidal volume prone patients with severe ARDS (P/F <150 in 2017 guidelines)	
	no recommendation	Against high frequency oscillatory ventilation (HFOV)
	weak recommendation for noninvasive ventilation in select patients with sepsis induced ARDS	Unable to make recommendation on noninvasive ventilation

Rhodes A, Evans LE, Alhazzani W, et al. Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock: 2016. Crit Care Med [Internet] 2017;1.

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Sep 05, 2017 | Elizabeth A. Jackson, MD, FACC Authors: Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. Citation: 2017 Focused Update of the 2016 ACC Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. J Am Coll Cardiol 2017;Sep 5:[Epub ahead of print]. The following are key points to remember about the 2017 Focused Update of the 2016 American College of Cardiology (ACC) Expert Consensus Decision Pathway on the Role of Non-Statin Therapies for Low-Density Lipoprotein (LDL)-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease (ASCVD) Risk: At the time of the 2013 ACC/AHA Cholesterol guidelines, the panel found no supporting evidence for the routine use of non-statin drugs in combination with statins for the reduction of ASCVD events. Three years later, the ACC published its first expert consensus decision pathway related to the role of non-statin therapies for LDL-cholesterol lowering. Since then, additional evidence, in particular related proprotein convertase subtilisin/kexin 9 (PCSK9) inhibitors, has been published. The revised recommendations (published in September 2017) pertain to patients with clinical ASCVD with or without comorbidities on statin therapy for secondary prevention. The writing committee did not provide new or revised recommendations related to primary prevention groups (patients with LDL-C Thresholds for consideration of ASCVD risk reduction are percent reduction in LDL (current LDL compared to baseline LDL). Absolute LDL or non–high-density lipoprotein (HDL) levels may be considered for each of the four statin benefit groups. The groups are: 1) adults with clinical ASCVD; 2) adults with an LDL ≥190 mg/dl; 3) adults ages 40-75 years without ASCVD with diabetes mellitus (DM) and an LDL between 70 and 189 mg/dl; and 4) adults between ages 40 and 75 years without ASCVD or DM, with an LDL between 70 and 189 mg/dl, and an estimated 10-year risk for ASCVD of ≥7.5% (using the pooled risk equation). Consideration of non-statin therapies to provide adequate percent LDL lowering was based on evidence from two trials: 1) FOURIER, which included patients with clinical ASCVD with or without DM; and SPIRE-2, which included high-risk primary prevention patients and patients with familial hypercholesterolemia. Percent risk reduction for patients with clinical ASCVD, with or without comorbidities, is recommended to be ≥50% for all patients with clinical ASCVD and a baseline LDL level. Consideration for an LDL 100 mg/dl can be given as well. The recommendations to consider non-statin therapies to all patients with clinical ASCVD are based on evidence from FOURIER and IMPROVE-IT trials. Addition of non-statin therapies to maximally tolerated statin therapy is recommended to be considered among patients with clinical ASCVD when additional LDL lowering is desired. Addition of either ezetimibe or a PCSK9 inhibitor should also factor in patient preferences, costs, and route of administration in addition to percent of LDL lowering desired. For 25% additional LDL lower, a PCSK9 inhibitor may be preferred. Periodic measurement of lipids (to determine adherence and response to therapy) continues to be recommended including at the start of treatment, 4-12 weeks after initiation of a statin, and thereafter every 3-12 months as clinically indicated. The writing committee recommended monitoring lipids at 4-12 weeks after modification to LDL-lowering therapy, including the addition of a non-statin therapy. Keywords: Atherosclerosis, Cardiovascular Diseases, Cholesterol, Cholesterol, LDL, Consensus, Decision Making, Diabetes Mellitus, Dyslipidemias, Genetic Diseases, Inborn, Hydroxymethylglutaryl-CoA Reductase Inhibitors, Hyperlipoproteinemia Type II, Life Style, Lipids, Lipid Metabolism, Inborn Errors, Lipoproteins, Patient Compliance, Primary Prevention, Proprotein Convertases, Risk Assessment, Risk Factors, Risk Reduction Behavior, Secondary Prevention, Subtilisins < Back to Listings The latest European guidelines for the primary prevention of cardiovascular disease appear to reduce the number of patients eligible for statin therapy compared with other international recommendations, a new study shows. In a contemporary cohort of patients without cardiovascular disease, just 4% of adults would qualify for statin therapy according to the 2021 European Society of Cardiology (ESC) guidelines. Additionally, just 1% of women met the ESC criteria for a class I recommendation to start statins. These numbers contrast starkly with what's seen for other international guidelines, including recommendations from the UK's National Institute for Health and Care Excellence (NICE) and American College of Cardiology/American Heart Association (ACC/AHA). More than one-third of these same patients qualify for statins (class I recommendation) using the pooled cohort equation forming the backbone of the ACC/AHA guidelines, for example. Given this, researchers believe that the threshold for treatment should be lowered in the ESC guidelines to be more closely aligned with other international recommendations. "One of the reasons that cardiovascular risk is now so low is because preventive therapy with statins are widely used," lead researcher Martin Bødtker Mortensen, MD, PhD (Aarhus University Hospital, Denmark), told TCTMD. "By having such a high threshold for treatment, it has major implications because we may start to take patients off preventive statin therapy. The American and NICE guidelines are based on randomized trials, so we have evidence [statins] are beneficial in these low-risk patients. In my opinion, at least, the European guidelines should come closer to the American and UK guidelines." The 2021 ESC prevention guidelines recommend statin treatment based on the 10-year risk of atherosclerotic cardiovascular disease (ASCVD) using the updated Systematic Coronary Risk Evaluation (SCORE) model. As opposed to SCORE, which has been used since 2003, SCORE2 is age-specific, with different thresholds for treatment based on the patient's age, and predicts both fatal and nonfatal ASCVD events. "The vast majority of cardiovascular events are nonfatal, so you'd underestimate the number of events if you have a model that only uses fatal events," he said, referring to the original SCORE risk-prediction model. "The European SCORE2 model is actually very good. It has nice calibration and is better than the previous model, but the major problem is the risk thresholds for assigning statin therapy." Very Few Women Eligible For the study, published July 6, 2022, in JAMA Cardiology, the researchers wanted to assess the clinical performance of the 2021 ESC prevention guidelines, particularly how well it stacks up against others, such as the 2019 ESC/European Atherosclerosis Society (ESC/EAS) dyslipidemia guidelines and the ACC/AHA and NICE guidelines. To do so, they turned to the Copenhagen General Population Study (CGPS), which is a prospective cohort study of Danish adults. In total, 66,909 healthy people were included in the analysis and investigators used the low-risk version of SCORE2, which is intended for western European countries (those considered low risk based on age- and sex-standardized mortality rates from the World Health Organization). From the 2021 ESC guidelines, adults 40 to 49 years are eligible for statins if their 10-risk ASCVD risk is 7.5% or greater (class I recommendation). For those aged 50 to 69 years, statins are a class I recommendation if they have a 10-year risk of 10.0% or greater. Statins are a class II recommendation for those aged 40-49 and 50-69 years if the 10-year ASCVD risk is ≥ 2.5% or ≥ 5.0%, respectively, and other risk modifiers are present. The ACC/AHA also uses the risk threshold of 7.5% or greater for statin therapy for all patients (class I recommendation), while the 2014 NICE guidelines say statins are strongly recommended if the 10-year risk is 10% or greater based on QRISK3. The ESC/EAS dyslipidemia guidelines recommend statins if the 10-year risk of fatal ASCVD is 5% or greater based on the original SCORE and then provide class I/II recommendations based on LDL-cholesterol levels. Of those in CGPS, just 2,862 qualified for a statin (4%) according to the ESC guidelines. In contrast, 34% of adults would be eligible for a statin based on the ACC/AHA guidelines and 26% based on the NICE recommendations. Similarly, 20% would be eligible for statins using the 2019 ESC/EAS dyslipidemia guidelines. The sensitivity of the ESC, ACC/AHA, NICE, and ESC/EAS recommendations for detecting future SCORE2-defined ASCVD events was 12%, 60%, 51%, and 36%, respectively. Statin eligibility increased with age across the guidelines, but this was least pronounced in the 2021 ESC guidelines. Overall, almost no women aged 40 to 49 years had a 10-year risk of ASCVD 7.5% or greater and just 1% aged 50 to 69 years met the threshold for statins. In men aged 40-49 and 50-69 years old, 2% and 13% met the 10-year ASCVD risk threshold for statin therapy. One of the reasons why fewer people are captured for preventive therapy with statins using the ESC guidelines may be that the 10-year risk of ASCVD is now much lower in adults, at least in those aged 40 to 69 years, said Mortensen. To offset this, he suggests lowering the age-specific threshold for treatment, which they tested out in their analysis. If the risk threshold was reduced—down from 7.5% to 4% in men and 2% in women aged 40 to 49 years old, respectively—they saw a marked improvement in the sensitivity of SCORE2 with just modest reductions in specificity. To perform as well as the ACC/AHA model, the SCORE2 threshold for starting therapy in adults aged 40 to 69 years should be reduced to 5%. To match the performance of NICE and ESC/EAS, the threshold should be reduced to 6% and 7%, respectively. Mortensen noted that there are four SCORE2 risk models specific to different European regions based on their age- and sex CVD mortality risk, yet each uses the same threshold for starting preventive therapy. Lower Threshold or Focus on Lifetime Risk Ann Marie Navar, MD, PhD (University of Texas Southwestern Medical Center, Dallas), Gregg Fonarow, MD (University of California Los Angeles), and Michael Pencina, PhD (Duke University Medical Center, Durham, NC), all of whom have serve as editors for JAMA Cardiology, state that lowering the thresholds might be a short-term solution to ensure adults receive "safe, low-cost, effective therapy," but would require continuous updating as population risk evolves over time. This would be difficult for the guideline writing committees to sustain long-term. Instead, they recommend considering longer-term risk estimation, particularly for younger adults, because age plays such an outsized role in the current risk equations. Another solution would be to stop using 10-year predicted risk as the jumping off point for statins and instead focus on a risk-benefit approach that factors in lifetime risk and the benefits of LDL-lowering. While the ESC guidelines do "briefly mention" this approach, Navar et al say it's not clear how clinicians could apply this strategy in clinic. There is also a need for clearer guidance on how to incorporate risk modifiers into treatment decisions, they add. Overall, they state that if this new analysis is confirmed, the ESC may need to "revisit or augment their current guidelines to prevent a step backward in the use of statins in primary prevention."

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