Tristan Marquez is trim and physically active and, at age 55, has no signs of heart disease. But last fall, when her total cholesterol measured 260 and the so-called bad LDL cholesterol hit 173, her physician wanted to immediately start her on a cholesterol-lowering statin.

Marquez, a Los Angeles real estate agent, decided to first try to bring the numbers down without pills. She now loads up with fruits and vegetables, scrutinizes package labels to steer clear of saturated fats and salt, and hits the gym at least three times a week. “I live like a monk,” says Marquez. “If my doctor tells me to take a statin, I will. But I’d prefer to correct this without drugs.”

Like Marquez, millions of Americans who don’t have heart disease – and who might not even have elevated cholesterol – may be startled to be handed a prescription at their next check-up. Last November, the American Heart Association and the American College of Cardiology issued sweeping new guidelines for staving off heart disease, which, as the nation’s number one killer, will claim 600,000 lives this year. The new rules, in a revolutionary change aimed at improving prevention, significantly lowered the threshold at which someone’s risk profile is considered worrisome enough to merit medication, while doing away with specific cholesterol target numbers and hitting hard on lifestyle changes instead.

The shift could more than double the number of statin takers to 56 million, according to a Duke University study. The potent statins now making up the therapeutic arsenal – including Zocor, Lipitor, Crestor and Pravachol – work by reducing the amount of cholesterol produced by the liver. They can shrink LDL cholesterol by up to 60 percent, boost levels of the “good” artery-clearing HDL cholesterol, prevent the buildup of perilous fatty plaques, and reduce triglycerides, blood clotting and inflammation, all of which contribute to heart disease.

Under the previous guidelines, healthy people were advised to keep total cholesterol under 200 milligrams per deciliter and their LDL to a max of 160; 130 to 159 was borderline. Anyone with heart disease was encouraged to bring the LDL number down to less than 100; whittling it down to 70 was even better. People at some risk, who are obese or who have high blood pressure, for example, were told to aim for 130 or less. Based on a complicated formula that factored in five key risks (age, smoking history, blood pressure, HDL level and family history), people whose predicted likelihood of a heart attack over the next 10 years was 20 percent or greater were advised to consider drugs.

The updated recommendations expand the risk factors to include race, using a new online estimator to spit out a person’s 10-year and lifetime chances of being hit by heart attack and dying from cardiovascular disease, and, for the first time, of suffering a stroke. And they set the bar for a serious talk about statins at just 7.5 percent. Since up to 80 percent of cardiovascular disease is caused by unhealthy lifestyle habits such as smoking, carrying around extra pounds, eating fat-laden foods (story, Page 72) and being a couch potato, everybody is advised to stick to a healthy diet and get 40 minutes of exercise three or four times a week, cut back on salt, reduce sugar intake and keep saturated fat to 5 or 6 percent of calories.

“We got rid of the [cholesterol] targets because we couldn’t find evidence for any single number,” says Neil Stone, chairman of the expert panel convened to formulate new guidelines on managing cholesterol and a professor
of preventive cardiology at Northwestern University’s Feinberg School of Medicine. “But we found strong evidence for optimizing lifestyle and optimizing the best therapy, statins,” for people at risk. The guidelines also discourage the use of popular nonstatin drugs often prescribed to improve cholesterol levels, like niacin, Zetia and fibrates, as first-line therapies. Data on their effectiveness isn’t as extensive or impressive as that on statins.

From virtually the minute they were released, the guidelines expanding statin use have stirred up controversy. For people in the high risk category – they’ve had a heart attack or stroke; have undergone an angioplasty or bypass surgery; or have diabetes, clogged arteries, heart-related chest pain or off-the-charts LDL – the cholesterol-busters are lifesavers. Statins cut by about 25 percent the odds that these folks will have a cardiac event within the next 10 years, numerous studies show, and the risk of dying from heart disease is reduced by 15 to 20 percent if they take the meds for the rest of their lives.

But for people who are otherwise healthy, experts argue that the scientific evidence is pretty thin that statins help. “If you’ve had a heart attack, you need a statin. The evidence is overwhelming,” says Steven Nissen, former president of the American College of Cardiology and a cardiologist at the Cleveland Clinic. “In people who haven’t had a heart attack but still have high risk factors, like diabetes, there is very clear evidence that some of them will benefit. But exactly where you draw the line is very controversial.” In his own practice, Nissen continues to prescribe statins on a case-by-case basis.

If the new recommendations are followed to the letter, then nearly 13 million more people could be on the cholesterol lowering pills, according to a 2014 analysis by Duke Clinical Research Institute scientists, in addition to the estimated 43 million Americans who are eligible under the previous rules (right now, only about 25 million people actually do take them). This would translate to almost half of all U.S. adults between the ages of 40 and 75. For otherwise healthy adults over age 60, the proportion would rise to 77 percent, versus about 48 percent under the old standard. But this could save lives, according to Duke University biostatistician Michael Pencina, the lead author of the study. Over 10 years, he says, up to 475,000 heart attacks, strokes and cardiovascular deaths could potentially be prevented.

The new approach, which also for the first time tailors the risk calculations for African-Americans, is aimed at capturing the type of patients that keep doctors up at night: the seemingly healthy people who die suddenly of heart attacks every year. More than 500,000 Americans will suffer their first attack this year, and many will have had no previous warning signs.

“It’s one thing to have an intellectual discussion, but I take care of patients who’ve had heart attacks and strokes, Tristan Marquez decided to try some serious exercise and an overhauled diet before resorting to drugs.
scientists with the Cochrane Review collected the data from 18 different studies that encompassed nearly 57,000 people without signs of cardiovascular disease taking statins for prevention. Of 1,000 people on medication for five years, researchers found, 18 would avoid a major heart attack or stroke, or 1.8 people out of 100. “We’re talking about 5,000 patient years of treatment to avoid 18 events if the evidence we have is accurate,” says John Ioannidis, an epidemiologist at Stanford University School of Medicine. “Statins are among the most effective drugs we have, but many of the additional people who are now being offered these medications may not benefit.”

And they might have to cope with side effects.

The drugs can trigger liver and muscle damage, pain, stomach upset and diarrhea, loss of mental acuity and memory lapses. They may even boost the potential for diabetes – which triples chances of getting heart disease – in women who have gone through menopause (and presumably no longer have the heart-protective benefits of estrogen). While for most people these irritants are relatively mild, the clinical tests where they were uncovered only lasted for five or seven years. “What kind of problems will crop up after 30 years?” wonders Ioannidis. “We don’t know. And remember, even in large
When elderly patients develop defective heart valves, they often are not good candidates for conventional open heart surgery to fix the damage. Until recently, their options were limited and many died. Now, two new procedures offer them a second chance at vigor. “We’ve had patients who can’t walk without getting short of breath who are now ambulatory and feel great,” says Mathew Williams, co-director of the Heart Valve Center at New York-Presbyterian Hospital/Columbia University Medical Center.

One of the therapies, approved in 2012 and now becoming more widely available, addresses aortic stenosis, in which the aortic valves narrow and stiffen, preventing blood from flowing properly through the heart. It affects about 5 percent of people over age 75, and causes shortness of breath, chest pain, fatigue and fainting. Absent treatment, half the people who develop symptoms die within two years. For decades, standard therapy has been to open the chest wall, stop the heart and replace the faulty valve. In a much less invasive “transcatheter aortic valve replacement,” a new valve is either inserted into the aorta through a small incision between the ribs or threaded to the heart via catheter by way of the femoral artery in the groin. The surgeon wedges the replacement valve inside the natural one, pushing the faulty valve aside so the new valve takes over. Patients normally can go home within a couple of days.

The MitraClip, a clamp that won approval in the fall of 2013, is a minimally invasive solution for people with mitral regurgitation, which occurs when the leaflets of the mitral valve become floppy or stretched, and allow blood to leak backward with every heartbeat. MR is a progressive disease that boosts the risk of heart failure. For most of the estimated 4 million Americans with this condition, surgery to tighten the leaflets or to replace the leaky valve is the most effective way to correct the problem. However, when open heart surgery is too big a risk, the MitraClip can also be inserted by catheter. Physicians manipulate the clip so that, like a clothespin, it pinches the two sides of the valve together, reducing or eliminating the backward leakage and restoring normal blood flow through the heart. The procedure is offered only at a handful of hospitals, including New York Presbyterian, Cedars-Sinai in Los Angeles, the Cleveland Clinic and Atlanta’s Emory University Hospital. “There’s a real learning curve,” says William Gray, director of Endovascular Services at Columbia University Medical Center in New York City, which is also on the list.

Both new procedures can cause complications, such as infections and bleeding, and rarely, stroke or death. With the MitraClip, in rare instances, the valve can tear or the clip can become loose. But for patients too frail for regular surgery, experts say, they are game changers. – L.M.