

Medicine's Most Profitable Pill Is Based on Flawed Science

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STORY AT-A-GLANCE

- "A Statin Nation: Damaging Millions in a Brave New Post-Health World," written by Dr. Malcolm Kendrick, addresses the challenges with the conventional approach of using statins for the prevention of heart disease
- > The difference between relative and absolute risk is an important yet poorly understood concept that helps clarify the actual benefit of any given drug or treatment. These hazard ratios also need to be compared against the overall mortality rate to get a clearer view of a drug's benefit
- > Repatha is a lipid-lowering medication said to reduce the rate of heart disease death and myocardial infarction by 20%, yet the overall mortality rate in the Repatha group was higher than in the placebo group
- > Cholesterol is found in every cell in your body, where it helps to produce cell membranes, hormones (including the sex hormones testosterone, progesterone and estrogen) and bile acids that help you digest fat
- > Cholesterol is important for the production of vitamin D, which is vital for optimal health. When sunlight strikes your bare skin, the cholesterol in your skin is converted into vitamin D. It also serves as insulation for your nerve cells, and is important for general brain health and cognition

This article was previously published June 02, 2019, and has been updated with new information.

Note: Since this article was written two years ago the SARS-CoV-2 jab has likely become the most profitable drug ever produced.

Dr. Malcolm Kendrick, a general practitioner in Cheshire, England, is the author of three books. I've previously interviewed him about his book, "Doctoring Data: How to Sort Out Medical Advice From Medical Nonsense." Here, we discuss another one of his books, "A Statin Nation: Damaging Millions in a Brave New Post-Health World." which addresses the challenges with this conventional approach to heart disease prevention.

This is his second book on the topic of cholesterol. In the first one, "The Great Cholesterol Con: The Truth About What Really Causes Heart Disease and How to Avoid It," published in 2007, he addressed the basis behind the cholesterol controversy. "A Statin Nation" is basically a follow-up to that book, as many things have changed over the past 10 years.

For example, a number of new cholesterol-lowering agents have been brought to market that drive low-density lipoprotein (LDL) even lower than before. "A Statin Nation" also includes information on how to prevent heart disease. Sadly, there's still a lot of industry-backed propaganda about heart disease and statins going on. As noted by Kendrick:

"There's a group in the U.K. called the Cholesterol Treatment Trialists' (CTT) Collaboration. They've got all the data ... from the statin trials. They hold it. They won't let anyone else look at it, ever. They keep producing these meta-analyses showing how wonderful statins are and that they don't have adverse effects, and we're supposed to believe them.

Although they run a clinical trials unit, last time I looked, they earned well over \$400 million in funding from pharmaceutical companies almost entirely — those companies that produce cholesterol-lowering agents.

... [W]e have a completely biased organization paid hundreds of millions to hold all the data, and then tell us, 'No one else can look at it. By the way, you should believe everything we say.'

... [H]ow on Earth can this be allowed to happen? ... [S]omehow, these people have got themselves such a standing and status that we're supposed to go, 'Well, you said it. It must be right.' This is ridiculous."

The Most Profitable Drugs Created in Medical History

In "A Statin Nation," Kendrick points out that by 2019 statins were the most profitable drugs ever created, grossing more than \$1 trillion. That's \$1,000 billion — a truly astounding statistic.

"I'm not entirely sure my trillion figure is exactly right, but it's not far off,"

Kendrick admits. "Other people have tried to calculate it. We know that Lipitor ...

at its max, was making about \$35 billion a year. That's just one statin in one

year ... Almost all of them have made billions each year ...

When you look at those amounts of money, that really funds an awful lot of marketing. ... [A] lot of people can be paid very large sums of money to attend meetings and run guidelines.

When I last looked at the guidelines of the National Cholesterol Education Panel — when they came out with the latest guidelines saying cholesterol should be lowered even more — out of nine ... in the committee, there were 124 conflicts of interest with companies making statins or other cholesterol-lowering agents. It's not surprising that we get the answers that we do, is it really? ... [W]hat else do we expect is going to happen?"

Relative Versus Absolute Risk

It may be helpful here to review a central concept addressed in Kendrick's earlier book, namely the difference between relative and absolute risk. This is an important yet poorly understood concept that helps clarify the actual benefit of any given drug or treatment. Kendrick says:

"I've asked about 50 medical colleagues this question, 'What's the difference between absolute and relative risk?' None of them has given me the correct answer. That's ... worrying ... When people go to their doctors, they expect their doctor to tell them what the benefits are, [yet] the doctors don't understand the benefits themselves ...

I've tried to explain this as simply as possible. Someone said, 'The difference between absolute and relative risk is the difference between multiplication and addition."

Here's a simplified example: Let's say you start 100 people on a medication and 100 people on placebo. At the end of the trial, you find that one person died in the treatment arm and two people died in the placebo arm. The relative risk is the difference in the number of deaths between the two treatment groups.

In this case, it's the difference between one death and two deaths. In the treatment group, the death rate was half of that in the placebo group, hence the relative risk is 50%.

The absolute risk is calculated by looking at how many are still alive. In the drug treatment group, 98 are still alive and in the placebo group, 99 people are alive. The difference between these two groups is now 1%. So, while the relative risk is 50%, the absolute risk is minuscule at just 1%.

Relative Risk Ratio Does Not Tell a True Story

Kendrick further explains:

"... [I]f you run an experiment with 1,000 people instead of 100 people, and at the end of the trial you get the same result ... one person died in the treatment arm and two people died in the placebo arm — then there's still a relative difference of one and two ... [which] is 50%.

But the absolute difference is between 999 and 998. That is 0.100%. If you keep running these figures, the relative risks can look incredibly impressive — there can be a 50% relative reduction in something — but the absolute reduction could be 0.0000001 or 0.0000002.

What the industry has recognized is that people see these figures, like a 36% [relative] difference in heart attack rate. The other thing they do is they don't even mention overall mortality ... Of course, it's the most important question because you don't take a drug just to die of one thing and not to die of another thing.

I'll use the example of when you push people off cliffs, then 100% of them will avoid dying from heart disease. You could say, 'I could reduce the risk of dying of heart disease to zero percent by pushing people off cliffs.' You may not think it's a good intervention, but the overall mortality is the key important thing, because ... people die more of liver cancer or kidney failure or muscle breakdown [when they take statins].

We see this happening when people discuss the new medications. Repatha is a new lipid-lowering medication. It was presented as being absolutely fantastic in reducing the rate of heart disease death and myocardial infarction by 20% [relative hazard ratio, when taken combined with a statin].^{3,4}

But when you looked at the absolute figures for death, more people died on the Repatha than on the placebo. More people died, and more people died of heart disease as well. This was presented as if it was a fantastic success.

We have a drug that is enormously expensive, and more people will be dead if they take it than if they don't take it. Yet, the pharmaceutical industry manages to present this as a resounding, outstanding success. It's quite extraordinary."

Kendrick also points out that unless an observational study produces a hazard ratio (relative risk ratio) of at least 200%, it's essentially worthless. This figure of 200% was

identified as a cutoff for relevancy by Richard Doll and Bradford Hill, two researchers looking at the effects of tobacco smoking.

The pair ended up devising standards for causation in observational studies, noting that when you're doing an observational study, your hazard ratio (relative risk ratio) needs to be greater than two (i.e., 200%) in order to have any relevance due to the many variables involved.

Next-Gen Cholesterol Drugs Are Just as Dangerous as Statins

While some of the dangers of statins are becoming more widely recognized, the dangers of cholesterol-lowering drugs in general are still being swept under the rug as newer drugs are released. A newer class of cholesterol-lowering drugs is the proprotein convertase substilisin/kexin type 9 (PSCK9) category.

Just as there are many different drugs within the statin category, there are many in the PSCK9 category. Repatha is one of them. These drugs tend to be far more expensive than statins. Repatha, for example, cost about \$14,000 per year, more than \$1,000 a month, until October 2018, when Repatha's manufacturer, Amgen, announced they were lowering the price to \$5,850 a year in response to competitors lowering their prices.⁵

Regardless of the reduced price, research still shows more people died on Repatha than in the placebo group, and I believe we'll end up finding the entire PSCK9 class of drugs will increase mortality.

Low-End Cholesterol Limit Has Been Eliminated

Over the years, cholesterol limits have gotten lower and lower, without any significant evidence proving that lowering cholesterol or LDL will in fact improve health and lower mortality. There's also no normal or average level of cholesterol either.

"There used to be, but there isn't anymore," Kendrick says. "There's optimal, but there's no lower limit. It's gone. We've reached a point whereby any level of cholesterol is now considered to be too high and any level can benefit from being lower, which is completely bonkers."

Indeed, it's tragic, since low cholesterol can have far-ranging consequences for your health. Cholesterol is found in every cell in your body, where it helps to produce cell membranes, hormones (including the sex hormones testosterone, progesterone and estrogen), and bile acids that help you digest fat.

It's also important for the production of vitamin D, which is vital for optimal health. When sunlight strikes your bare skin, the cholesterol in your skin is converted into vitamin D. It also serves as insulation for your nerve cells, and is important for general brain health and cognition.

Low levels of high-density lipoprotein (HDL) cholesterol have been linked to memory loss and Alzheimer's disease, and may also increase your risk of depression, stroke, violent behavior and suicide.

Why Kendrick Doesn't Worry About 'High' Cholesterol

Kendrick himself does not worry about high cholesterol. His own level is 300, and he says he'd actually like it a bit higher. He explains why:

"[I] wrote a paper with a few other doctors where we looked at the cholesterol levels and death rates in populations. What we found is that once you reach the age of 55 to 60-ish, those with higher cholesterol levels live longer than people with lower cholesterol levels. It's not huge. It's not a gigantic difference, but it exists.

... [T]hat's true even in people who have familial hypercholesterolemia. There's a small subgroup of people with familial hypercholesterolemia who will die young. We wrote a paper on that demonstrating it has nothing to do with the cholesterol or LDL level. It has to do with blood-clotting factors ...

[Y]ou can have siblings, one of whom has hypercholesterolemia, the other does not ... They both have the clotting factor, and ... they have the same risk of dying of heart disease because, actually, the LDL receptor itself, the thing that takes LDL out of the system, also takes Factor VIII out of the system as well ...

The thing that is probably damaging in familial hypercholesterolemia in some people is not the high LDL or the high cholesterol level, it's the fact that the clotting factors are not being taken out by the receptors ...

People communicate with me quite regularly saying, 'My LDL level or my total cholesterol level is 600, 700 or 800' ... [To paraphrase] Karl Popper ... 'If your hypothesis is that all swans are white, then finding another white swan proves very little. Find a black swan and your hypothesis is dead.'

I know, directly, of more than 50 people whom I've communicated with who have cholesterol levels that are three to four times the normal. Their LDL levels can be five to six times the normal with no discernible heart disease ... When people say to me raised cholesterol causes heart disease, [I counter saying] the evidence just doesn't [show] this."

It's also worth pointing out that only 20% of the cholesterol in your bloodstream comes from dietary sources; the remaining 80% is made by our own body⁶ and, as noted by Kendrick, your body is designed to deal with wide variations in dietary cholesterol intake.

"What happens if you eat more cholesterol? Your body produces less cholesterol because it doesn't need to anymore. Perhaps you can overwhelm it, but I have seen studies where people have tried to overwhelm [the body with cholesterol] and ... There's a kind of shuttle system.

Once your cholesterol levels are full and you don't need any more, [your body] doesn't absorb cholesterol anymore. It just shuttles it back out again. It just goes straight through you and out the other end. Your body can control these things. And the idea that some minute amount of added [dietary] cholesterol is

going to overwhelm your control systems, [that] just goes against all known human physiology. It's ... complete nonsense."

People With Higher Cholesterol Live Longer

Kendrick cites a number of studies refuting claims that high cholesterol increases your risk of heart disease and death. For example:

 A Norwegian study⁷ published in 2012, which assessed the cholesterol levels and rate of ischemic heart disease death among 50,000 people over a period of 10 years, found that as women's cholesterol levels went up, their risk of death went down.

"Women who had LDL levels of 300 to 400 were 40% less likely to die from ischemic heart disease as women who had an LDL level or cholesterol level of 200 or less," Kendrick says. As noted by the study authors:

"Our study provides an updated epidemiological indication of possible errors in the CVD risk algorithms of many clinical guidelines.

If our findings are generalizable, clinical and public health recommendations regarding the 'dangers' of cholesterol should be revised. This is especially true for women, for whom moderately elevated cholesterol (by current standards) may prove to be not only harmless but even beneficial."

- An Austrian study, which included hundreds of thousands of people between the ages of 15 and 95, found the same thing. If your cholesterol level was lower, you were more likely to die younger. "Now, the difference wasn't enormous, but it existed. The only population where they didn't find that was in younger men," Kendrick says.
- A Japanese group of researchers looked at 12,000 women with total cholesterol over 300. "Over a 12-year period, not one of them died from ischemic heart disease,

not one," Kendrick says.

- Zoe Harcombe, Ph.D., a U.K. researcher, looked at World Health Organization data from all the countries in the world that measure and track cholesterol and rates of cardiovascular death, and found that as cholesterol levels went up, the rate of death from heart disease went down.⁸
- Even the Framingham Heart Study⁹ found that "over a 32-year period of research, the most dangerous thing that could happen to you is your cholesterol level started to fall," Kendrick says.

"If memory serves, for about a 10% reduction in your cholesterol level, the risk of cardiovascular death went up 500%. That's a relative risk, not an absolute risk. But it's still pretty gigantic.

[Yet] even the Framingham study contradicts itself. They said that for every 1% fall in LDL or cholesterol there was a 2% fall in cardiovascular death. That figure doesn't exist anywhere. Where does it come from? It's just been made up, and it's widely quoted everywhere ... People believe things where the facts don't exist. They're not supported."

Statins Are Associated With Grave Adverse Effects

Statins are associated with a range of serious side effects, including muscle aches and muscle damage. They also inhibit not only the production of cholesterol but Coenzyme Q10 (CoQ10), required by your mitochondria for the creation of cellular energy in the form of adenosine triphosphate (ATP). Without sufficient ATP production, you die.

According to Kendrick, drug companies have known from the start that statins reduce CoQ10 by 40 to 50%, but didn't follow through on plans to require statins to be prescribed with CoQ10 as this might tip people off to the fact that statins might not be so beneficial after all.

"... [O]ne of the most worrying things is the statistics for heart failure have really started to rise and go through the roof ... yet ... people are not looking at this in association with statins. But your heart's a muscle. Your heart needs CoQ10. People are getting heart failure. Why is this not being picked up?" Kendrick says.

"Another really... adverse effect that has been picked up — WHO first noted this — was an association with amyotrophic lateral sclerosis, which is, in America, known as Lou Gehrig's disease ... It's a really horrible motoneuron disease. More recently ... it was found that taking statins was associated with ... a 20,000% increase in the risk [of Lou Gehrig's] ...

Our bodies need cholesterol. Our neurons need cholesterol. Our brain synthesizes cholesterol in specific cells. They put it in your myelin sheaths ... that protect the neurons. Without it, who knows what's going to happen?

There's definitely an increase in Parkinson's disease and other neurological conditions. That's been shown in several studies. It's been dismissed ... This is where I'm really worried ... People are getting serious ... neurological problems from statins, and it's just being dismissed."

Benefit of Statins Can Be Replicated Without Risk

As for the benefits sometimes seen in studies, Kendrick is convinced these benefits are not due to the drug's ability to lower cholesterol but rather its ability to increase nitric oxide synthesis in your endothelial cells, 10,11 which has an anticoagulant effect and causes vasodilation. Nitric oxide also stimulates the production of new endothelial cells in your bone marrow.

"I think that, on its own, could explain any benefits you see from statins," he says, "because when you look at the clinical trials ... the benefits of statins are seen almost immediately, like after a week or two ... And then it kind of plateaus

out. If it were to do with lowering cholesterol and stopping plaques from forming, it should surely take years to see any benefit."

The bottom line is there may be other pleiotropic benefits to taking statins unrelated to lowering cholesterol. However, it's an expensive and dangerous way to get that benefit when boosting nitric oxide can easily, inexpensively and safely be done through exercise and dietary means.

Another likelihood is that statins also increase the Nrf2 pathway, and likely also increase NADPH, which are both highly biologically useful, but there are far safer and less expensive strategies to provide these benefits as well.

What About the Cholesterol Found in Plaque?

Part of the confusion that makes it hard for people to let go of the simplistic idea that cholesterol will form plaque buildup in your arteries is that plaque does contain cholesterol. However, this cholesterol has nothing to do with your LDL level, Kendrick insists.

"The interesting thing is ... you can't get a cholesterol crystal from the cholesterol carried around in LDL, because the cholesterol carried in LDL is what we call the cholesterol ester. It's a cholesterol attached to a fatty acid. Two molecules stuck together, that's what they call cholesterol ester. You can't make a crystal from that ...

[S]o where does it come from? The only place we could get a cholesterol crystal from in the body is from the membranes of red blood cells, because the membrane of a red blood cell contains more free cholesterol than anything else in the body ... Where do red blood cells come from? Well, it's got nothing to do with LDL. We know that.

The other interesting fact is that when we find things that look like LDL, they're almost certainly not LDL. They're almost certainly another lipoprotein called [lipoprotein A] (LPA), because LPA and LDL are exactly the same thing, except

LPA has another protein attached to it called apolipoprotein A ... [which] is identical in structure, apart from one amino acid, to plasminogen.

Plasminogen ... is incorporated into blood clots as they form. Plasminogen can be turned into plasmin by tissue plasminogen activator, and that's what splits clots apart. However, if you have a clot with LPA in it ... the plasminogen activator cannot work, and that clot cannot be broken apart and remains stuck ...

Therefore, when you have LPA involved when you've got arterial damage, then you get a blood clot, you get LPA, you get red blood cells, and then you have a blood clot attached to the side of your blood vessel ... Then you're left with a situation.

Well, what [does your body do with this blood clot]? It can't fall off and travel down the artery. It would just block the artery further down. So ... the body shaves it off. Then when it's shaved it down, new endothelial cells floating around in the blood cover it over, so you then have a blood clot lying underneath of a new layer of endothelium.

That blood clot is the formation. The direct result of that over time — if it keeps happening on that spot over and over again — that becomes plaque-containing cholesterol crystals."

More Information

To learn more, consider picking up a copy of Kendrick's book, "A Statin Nation: Damaging Millions in a Brave New Post-Health World." Interestingly, Kendrick presents evidence suggesting the strongest risk factor for dying from heart disease is mental stress and mental illness, and by a significant margin, compared to anything else, including diet.

As for food, the evidence clearly points to sugar and excess carbs being a primary culprit in heart disease, as well as processed vegetable oils. According to the American

Heart Association,¹² in 2022 49.2% of American adults now have some form of cardiovascular disease, and deaths from cardiovascular disease is again on the rise after decades of decline. Clearly, we're doing something very wrong, and statins and PSCK9 class drugs are likely only contributing to the problem.

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