Records Found in Dusty Basement Undermine Decades of Dietary Advice

Raw data from a 40-year-old study raises new questions about fats

BY SHARON BEGLEY & STAT



If biology has an Indiana Jones, it is Christopher Ramsden: he specializes in excavating lost studies, particularly those with the potential to challenge mainstream, government-sanctioned health advice.

His latest excavation—made possible by the pack-rat habits of a deceased scientist, the help of the scientist's sons, and computer technicians who turned punch cards and magnetic tape into formats readable by today's computers—undercuts a pillar of nutrition science.

Ramsden, of the National Institutes of Health, unearthed raw data from a 40-year-old study, which challenges the dogma that <u>eating vegetable fats</u> instead of animal fats is good for the heart. The study, the largest gold-standard experiment testing that idea, found the opposite, Ramsden and his colleagues <u>reported</u> on Tuesday in BMJ (formerly the British Medical Journal).

Although the study is more than just another entry in the long-running <u>nutrition wars</u>—it is more rigorous than the vast majority of research on the topic—Ramsden makes no claims that it settles the question. Instead, he said, his discovery and analysis of long-lost data underline how the <u>failure to publish</u> the results of clinical trials can undermine truth.

Absent a time machine, it's impossible to know how publication of the study, conducted in Minnesota from 1968 to 1973, might have influenced dietary advice. But in an accompanying editorial, Lennert Veerman of Australia's University of Queensland concluded that "the benefits of choosing polyunsaturated fat over saturated fat seem a little less certain than we thought."

The Nixon-era experiment had produced only a single journal paper, in 1989, which concluded that replacing saturated fats found in meat and dairy products with vegetable oils did not reduce the risk of coronary heart disease or death. But it had few quantitative data and little statistical analysis, and was silent on many of the questions the researchers told NIH, which funded it, they intended to answer.

Ramsden wondered if there was more data from the study somewhere.

In 2011, he sought out the sons of the experiment's principal scientist, Dr. Ivan Frantz of the University of Minnesota, who died in 2009.

"I told him I recalled lots and lots of records, whole chests full of records—IBM [computer] tapes—back in Minnesota," said Dr. Ivan Frantz III, a neonatologist at Beth Israel Deaconess Medical Center in Boston.

Dr. Robert Frantz, a physician at the Mayo Clinic, drove 90 minutes to his childhood home, to search file cabinets. On his third trip he spied moldering, unlabeled boxes in the far corner of the basement. Inside were ancient magnetic computer tapes and reams of yellowed documents. The subject line in his email to Ramsden was "Eureka."

After getting the tapes translated into formats that modern computers can read, Ramsden and his colleagues discovered what had been hidden for nearly

half a century: records on 9,423 study participants, ages 20 to 97, all living in state mental hospitals or a nursing home. It was the largest experiment of its kind.

It was also one of the most rigorous. Participants were randomly assigned either to the group eating the then-standard diet, which was high in animal fats and margarines, or to a group in which vegetable oil and corn oil margarine replaced about half of those saturated fats. Such a randomized controlled trial is considered less likely to produce misleading results than observational studies, in which volunteers eat whatever they choose. Observational studies are weaker than randomized ones because people who eat one way, rather than another, might have characteristics that benefit their heart health.

And because the Minnesota participants were in institutions that prepared all their meals and kept records, the scientists knew exactly what they are for up to 56 months. Many nutrition studies have foundered because people misremember, or lie about, what they are.

Analyzing the reams of old records, Ramsden and his team found, in line with the "diet-heart hypothesis," that substituting vegetable oils lowered total blood cholesterol levels, by an average of 14 percent.

But that lowered cholesterol did not help people live longer. Instead, the lower cholesterol fell, the higher the risk of dying: 22 percent higher for every 30-point fall. Nor did the corn-oil group have less atherosclerosis or fewer heart attacks.

The study has some flaws, not unexpected for one from half a century ago, said Dr. Nortin Hadler of the University of North Carolina, who was not involved

in the research. It's possible that the saturated-fat group and the corn-oil group differed in ways that accounted for the latter's worse health and higher mortality, for instance; the Minnesota team apparently didn't investigate that possibility.

"It's impossible to do a perfect trial," Hadler said. "But this was as good as it got at the time and not bad today. It tested the [diet-heart] hypothesis and rejected it."

The hypothesis holds that vegetable oils rich in linoleic acid, like safflower and corn, are good for heart health, that saturated fats, such as those in red meat and dairy products, clog arteries and are very bad, and that replacing the latter with the former reduces deaths from heart attacks, heart disease, and strokes by lowering blood cholesterol levels.

In 2014, for instance, nutrition scientists and epidemiologists <u>concluded</u> from an analysis of 13 studies that consuming more linoleic acid, the kind the Minnesota participants substituted for saturated fat, is associated with lower risk of cardiovascular disease, and that more is better, "provid[ing] support for current recommendations to replace saturated fat with polyunsaturated fat" to prevent heart disease.

But all 13 of the studies were observational.

Partly because of the weak evidence for the diet-heart hypothesis, it has been under increasing assault. Critics of the demonization of saturated fat have long pointed out that key findings from landmark studies were never published. One, the Seven Countries Study, originally included many more nations. But in only seven did populations consuming lots of saturated fats have high levels of heart disease, prompting recent accusations of cherry-picking data.

That 1970 study was hugely influential, however, leading to congressional hearings and guidelines advising against eating saturated fat and arguing for the benefits of polyunsaturated fats.

Other recent analyses, too, have questioned the demonization of saturated fats and the dogma that vegetable oils are healthier. For instance, a 2014 analysis of 78 studies involving some 650,000 people found that "neither lower consumption of saturated fats nor higher consumption of polyunsaturated fats reduces the risk of developing cardiovascular disease," said epidemiologist Dr. Rajiv Chowdhury of the University of Cambridge, the lead author.

In 2013, Ramsden resurrected <u>another long-lost randomized study</u>, the 1960sera Sydney Diet Heart Study. Reanalyzing its unpublished data—also stored on old nine-track computer tapes—he found that volunteers who replaced much of the saturated fat in their diet with polyunsaturated fats high in linoleic acid had a higher risk of death from coronary heart disease.

For their new paper, Ramsden's team also reviewed and analyzed all randomized controlled trials of substituting polyunsaturated fats for saturated fats. There have been only five. Bottom line: they reduce cholesterol, but not deaths from coronary heart disease or other causes.

"This certainly raises question about the diet-heart hypothesis," said Ramsden, whose search for lost studies is only a side project (his main research is on the biochemistry of linoleic acid). "Nothing in this study shows that there are benefits of saturated fats," as studies like Chowdhury's have suggested. "But maybe they're not as dangerous as decades of dietary advice have claimed, and replacing them with polyunsaturated fats is not beneficial either."

Which is not to say that this lost study will change views on dietary fat and heart health. Positions on all sides seem set in concrete, and in any case, dietary advice is moving away from a focus on components, such as fat, and toward actual foods.

"At the end of the day, modern nutrition science now shows us that with a few exceptions such as ... trans fat and sodium, the health effects of what we eat depend on the types of foods we eat, not single nutrients," said Dr. Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science & Policy. "Many lines of evidence show that vegetable oils/fats are healthy and reduce risk of cardiovascular disease."

No one knows why the Minnesota results were not published decades ago. Franz lived and breathed science, his sons recall, to the extent that he would have his wife, a nurse, draw his children's blood so he would have more to study. Bob Frantz recalls trooping to his father's university lab before Saturday morning football to watch centrifuges spinning his and his brothers' blood (and to have the clam chowder his father heated on Bunsen burners).

The Frantz children always felt fortunate that their father brought his work home, his beliefs about the dangers of saturated fat shaping what the family ate. "Other kids would have ice cream; we had ice milk," recalled Ivan Frantz. Bob said they were "reared on margarine," foreswearing butter's saturated fat.

It's possible, Bob Frantz said, that his father's team was discouraged by the failure to find a heart benefit from replacing saturated fats with vegetable oils. "My feeling is, when the overall objective of decreasing deaths by decreasing cholesterol wasn't met, everything else became less compelling," he said. "I suspect there was a lot of consternation about why" they couldn't find a benefit.

The coleader of the project was Dr. Ancel Keys, author of the Seven Countries Study, Time cover subject, and the most prominent advocate of replacing saturated fat with vegetable fat. "The idea that there might be something adverse about lowering cholesterol [via vegetable oils] was really antithetical to the dogma of the day," Bob Frantz said.

His father, he said, "was always committed to discovering the truth. He would be pleased this is finally coming out."

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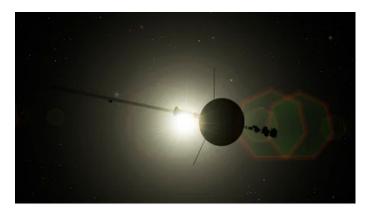
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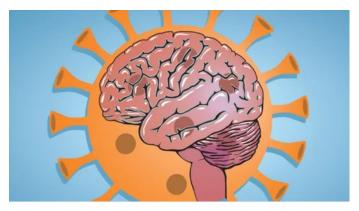
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