



DATA 8
Spring 2022

Lecture 38

Case Study: Health

Announcements

Introduction

“The Basement Tapes”

Dr. Ivan Frantz Jr. (1916-2009) was principal investigator of the NIH-funded **Minnesota Heart Study** that linked diet, cholesterol, and heart disease.

His son **Dr. Robert Frantz**, cardiologist at the Mayo Clinic, received a message in 2011 (just after his father's death):

“Dr. Frantz, I've heard the possibility that there might be some very interesting data in your father's basement.”

Malcolm Gladwell, for his podcast **Revisionist History**, interviewed Dr. Robert Frantz (Season 2, Episode 10).

Finding Lost Data

Christopher Ramsden (NIH) “specializes in excavating lost studies, particularly those with the potential to challenge mainstream, government-sanctioned health advice.” [1]

- Failure to publish studies that do not confirm a hypothesis can mislead the scientific community.
- Understanding and publishing historical data can be a productive alternative to conducting new studies.
- Research interest in the effect of linoleic acid consumption on human health. (Linoleic acid provides perhaps 10-15% of calories consumed today.)

[1] <https://www.scientificamerican.com/article/records-found-in-dusty-basement-undermine-decades-of-dietary-advice/>

The Diet-Heart Hypothesis

Cardiovascular Disease

- *Atherosclerosis* narrows arteries due to plaque buildup.
- #1 cause of death and disability in the developed world.
- Cardiovascular disease (CVD) is the leading global cause of death: 18.6 million deaths in 2019.
- The causes are not known, but there are associations with high blood pressure, diabetes, smoking, obesity, family history, age, inactivity, and an unhealthy diet.

Diet & Cardiovascular Disease

- Associated with unhealthy diet, physical inactivity, tobacco use, high intake of alcohol.
- 1.7M deaths worldwide are attributed to low fruit and vegetable consumption by the WHO (2011).
- High intake of salt is linked to high blood pressure.
- High intake of processed foods is linked to obesity.
- Eliminating trans fats is widely recommended.
- Added sugar is linked to high blood pressure & obesity.

The Diet-Heart Hypothesis

Hypothesis:

- Replacing saturated fat (e.g. dairy) with polyunsaturated fat (e.g. plant-based oil) reduces risk of heart disease.

Justification:

- This replacement reduces serum cholesterol.
- Serum cholesterol is associated with heart disease.
- "Clinical trials that used polyunsaturated fat to replace saturated fat reduced the incidence of CVD." (AHA, 2017)

Hypothesis Testing

Designing an Experiment

Hypothesis:

- Replacing saturated fat (e.g. dairy) with polyunsaturated fat (e.g. plant-based oil) reduces risk of heart disease.

What evidence would support this hypothesis?

Minnesota Coronary Experiment (1968-1973)

Experimental Design

- How do you know that subjects will follow the diet they are assigned and report their consumption accurately?
 - **Closed population:** subjects were institutionalized individuals fed out of cafeterias in every meal.
 - Control group: food was cooked in butter and served with butter, as usual.
 - Treatment group: food was cooked in vegetable oil and served with margarine (corn-based substitute)
 - **Double-blind** study: neither the subjects nor the people delivering the treatment (food servers) knew whether
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Outcome

- Study continued for five years, tracking both subject cholesterol levels and health outcomes.
 - Malcolm Gladwell: “The patients on the vegetable oil died **did end up with lower cholesterol** than the people who ate food cooked with animal fats, that part worked according to expectation. But the vegetable oil people **didn't live longer.**”
 - Master's thesis by Steve Broste contained some analysis of the data, but was not published.
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Steve Broste: And they were hoping that, with some new statistical techniques that'd just come out, that they might be able to either understand why the results came out the way they did or perhaps, after some adjustments for various explanatory factors, that maybe the results would, would change.

Malcolm Gladwell: The results didn't change. When Broste talked to Ivan Frantz, Frantz just shook his head.

Steve Broste: I remember him just expressing his, his bewilderment at, at how this could possibly have happened.

Data Collected

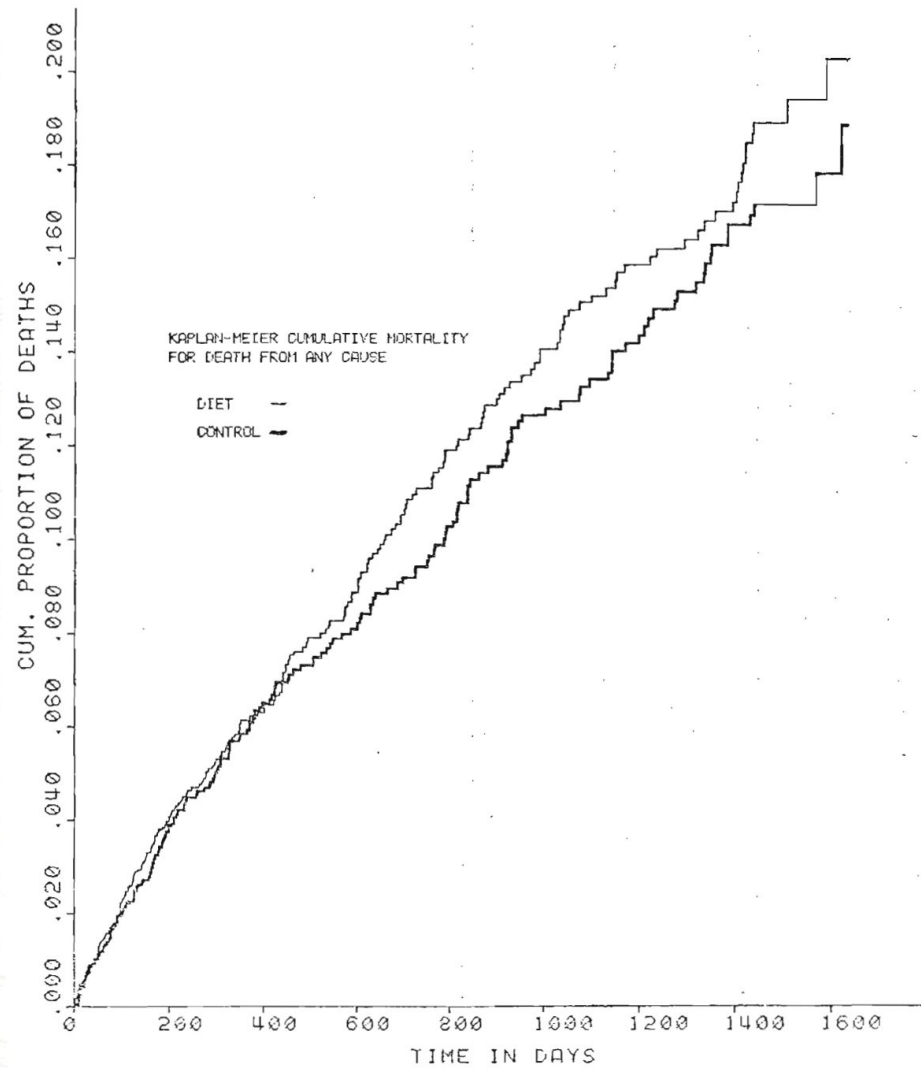
Robert Frantz returned to his childhood home multiple times to search the basement for records.

Emailed Ramsden after third trip with the subject: “Eureka”

He had discovered whole chests full of IBM computer tapes, including records on 9,423 study participants, ages 20 to 97, all living in state mental hospitals or a nursing home — the largest experiment of its kind.

Reanalysis and Conclusion

“Conclusions: ... Replacement of saturated fat in the diet with linoleic acid effectively lowers serum cholesterol but does not support the hypothesis that this translates to a lower risk of death from coronary heart disease or all causes. Findings from the Minnesota Coronary Experiment add to growing evidence that incomplete publication has contributed to overestimation of the benefits of replacing saturated fat with vegetable oils rich in linoleic acid.”



Broste Thesis Figure 6

Number of Deaths by Age and Randomization Group

Age	Diet			Control		
	Randomized	Died	%	Randomized	Died	%
LT 35	1367	3	0.2	1337	7	0.5
35-44	728	3	0.4	731	4	0.5
45-54	767	14	1.8	816	16	2.0
55-64	870	35	4.0	896	33	3.7
GE 65	953	190	19.9	958	162	16.9
TOTAL	4685	245	5.2	4738	222	4.7

(Demo)

Other Clinical Trials

Controlled Experiments

- Wadsworth Hospital and Veterans Administration Center in Los Angeles evaluated a diet [using] corn, soybean, safflower, and cottonseed oils, all high in polyunsaturated linoleic acid, to replace saturated fat in the control diet (846 *men; mean age of 65 years; 30% had CVD; 8 year duration*).
- Oslo Diet-Heart Study evaluated changing to a low saturated, high polyunsaturated fat diet (412 *men with prior MI*).
- British Medical Research Council compared a diet containing soybean oil, 86 g/d, with a diet with saturated fat from animal products (393 *men with prior MI*).

Finnish Mental Hospital Study

"The Finnish Mental Hospital Study compared a diet high in polyunsaturated fat, mainly from soybean oil, with a diet high in saturated fat in 1222 patients at 2 psychiatric hospitals. In 1 hospital, the high polyunsaturated fat diet was given first, followed by the saturated fat diet; in the other hospital, the diets were given in the reverse order (*1222 patients; 6 years*)."

- Non-blind & conditions evaluated at different times.
- "The amount of sugar in the diet varied by almost 50%."
- "The use of psychiatric drugs with known cardiovascular side effects differed substantially between groups."