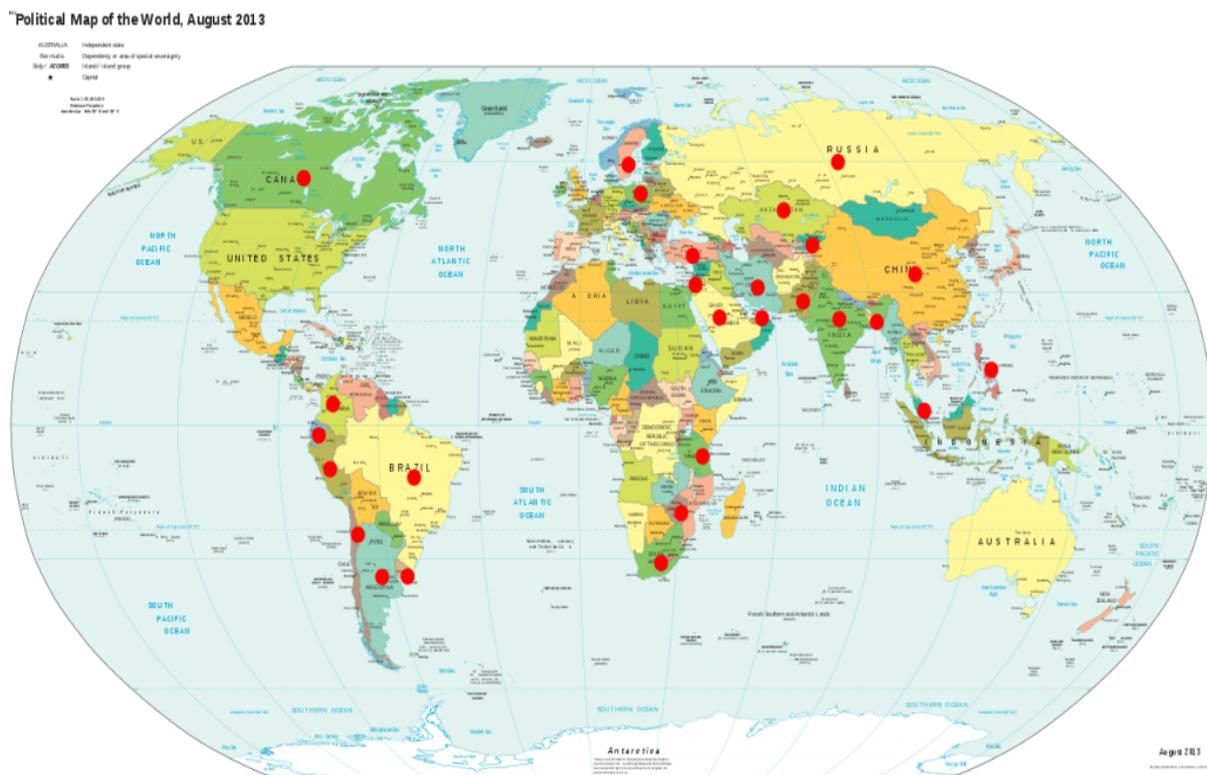


Dr James Muecke is the Australian of the Year in 2020 which was awarded for his work as an eye-surgeon and his work in preventing blindness.

Muecke believes that we should be eating more eggs, cheese, meat and dark chocolate to minimise diabetes, its associated blindness (diabetic retinopathy) and diabetic neuropathy. Peripheral diabetic neuropathy is nerve damage of the limbs that is caused by diabetes. 50% of adults with type 2 diabetes have peripheral neuropathy. It can result in pain, numbness and an increase in sensitivity. Diabetes account for more than 80% of amputations.

Muecke cites the PURE Study to justify his low-carbohydrate, high-fat, animal-based diet.

The PURE Study is an observational study in 27 countries that examined 225,000 people. The study period is 20 years.



The 27 Countries of the PURE Study

The purpose of the PURE study is to examine the impact of urbanisation on the development of risk factors such as physical activity, nutrition changes, obesity, high blood pressure, abnormal blood sugars, abnormal blood lipids and smoking on heart disease.

18 of these 27 countries (Argentina, Bangladesh, Brazil, Canada, Chile, China, Colombia, India, Iran, Malaysia, Pakistan, Palestine, Poland, South Africa, Sweden, Turkey, United Arab Emirates, Zimbabwe) were used to examine mortality and cardiovascular events and their relationship to nutrient intake of carbohydrate, fats, and protein.

Very different countries with very different cultures and levels of development. It is very difficult, if not impossible, to make valid comparisons. ¹

The conclusions of the PURE Study that gained widespread attention were:

- higher the intake of carbohydrate (as a percent of calories), increased the risk of total mortality
- higher intake of fats lowered the risk (as a percent of calories) decreased the risk of total mortality
- higher intake of saturated fats lowered the risk (as a percent of calories) decreased the risk of total mortality

However, it was noted that a higher intake of polyunsaturated fats also decreased the risk of total mortality.

Many researchers have doubts on the very large, expensive but flawed study. The Harvard School of Public Health wrote a newsletter that stated: ²

PURE study makes headlines, but the conclusions are misleading. Last week, *The Lancet* published results from the Prospective Urban Rural Epidemiology (PURE) study that made headlines: “*Study Challenges Conventional Wisdom on Fats, Fruits, and Vegetables*”, “*PURE Shakes Up Nutritional Field*”, “*Huge New Study Casts Doubt on Conventional Wisdom About Fat and Carbs.*” [...] However, its findings are not as novel or disruptive as these sensational headlines suggest.

High-income countries (Canada, Sweden, United Arab Emirates) are being compared with low-income countries (Bangladesh, India, Pakistan, Zimbabwe). Low-income countries have a much greater increased risk of infectious diseases and diets are much more likely to be inadequate.

In Bangladesh, the biggest source of carbohydrates, protein and fat was white rice which is inadequate and not conducive to healthy outcomes. That is, white rice, rice with most of the protein and nutrients removed through hulling, is the biggest source of protein for the people

of Bangladesh. This is indicative of the very poor quality of the diet in Bangladesh. It is not valid to compare such a diet in with diets in European countries. Whilst the study details the percentage of energy from the macronutrients, it fails to document the most important item – the total amount of energy consumed which would show the Bangladesh diet having only a fraction of the total energy consumed than their more wealthy counterparts.

The PURE Study divided the study group into seven regions. The countries are not representatives of their regions. In the case of South Asia, the authors have selected three countries to represent their region and Malaysia is the sole representative of South East Asia. If Japan was included in the study, it would show different results.

- China
- South Asia (Bangladesh, India, Pakistan)
- Europe and North America (Canada, Poland, Sweden)
- South America (Argentina, Brazil, Chile, and Colombia)
- Middle East (Iran, occupied Palestinian territory, Turkey and United Arab Emirates)
- South East Asia (Malaysia)
- Africa (South Africa, Zimbabwe)

Comparing one middle income country in SE Asia (Malaysia) with three low income countries of South Asia (Pakistan, Bangladesh and India) and high income Europe is not conducive to meaningful results.

In many countries, there is a large regional variations in the diet. China, Japan, France, Italy, India are some examples.

In the data below, diabetes was defined as a fasting plasma glucose level ≥ 7.0 mmol/L or ≥ 11.1 mmol/L for non-fasting. Hypertension is defined as systolic blood pressure of at least 140 mmHg or diastolic blood pressure of at least 90 mmHg. The threshold for these definitions are high with optimal fasting glucose being 5.5-6.0 mmol/L and systolic blood pressure being less than 120 mmHg.

In India, there is a large variation in both dietary and non-dietary risk factors between the states.³

- Smoking – Women: Tamil Nadu (0.0%) to Mizoram (18%)

- Smoking – Men: Maharashtra (16%) to Mizoram (67%)
- Obesity (BMI \geq 25): Madhya Pradesh (8%) to Kerala (27%)
- Hypertension: Andhra Pradesh (17%) to Madhya Pradesh (21%)
- Diabetes – Women: Mizoram (0.5%) to Kerala (5.3%)
- Diabetes – Men: Madhya Pradesh (0.6%) to Kerala (6.5%)

Age-standardised diabetes prevalence for men rose from 3.7% to 9.1% for women from 4.6% to 8.3% between the years 1980 to 2014. ⁴

To attempt to relate health outcomes to primarily dietary factors is a pointless exercise.

PURE Study Conclusions

There were two other papers, written by the same authors that were published in the same *Lancet* journal. One examined the that examined the role of *Fruit, Vegetable and Legume (VFL)* intake on heart disease and concluded: ⁵

Higher total fruit, vegetable, and legume intake was inversely associated with heart disease and total mortality.

Some points to consider when evaluating this study. ⁶

- The role of trans fats has not been examined. In Asia, there is an increasing problem of trans fats. The use of hydrogenated vegetable oil (ghee) and shortening in the frying of samosa, paratha, bhatura, poori, and tikkies results in increased consumption of trans fats. There is a positive correlation between consumption of trans fats and cardiovascular disorders.
- The PURE study showed that, *Total carbohydrate consumption was associated to higher total and non-CVD mortality such as cancers and infections but not from heart disease.*
- However, all carbohydrates were grouped together with no distinction made with carbohydrates obtained from sugars added to food (for example, cereals, yogurt, chocolate), refined pure sugar, fruit juice, fruits and complex carbohydrates such as starches, inulin, vegetable gums and pectins. Failure to differentiate between types of carbohydrates gives a misleading picture.
- Note that the paper also stated that, **“Fruit, vegetables and legumes containing**

complex carbohydrates were associated with a lower total mortality.”

- Dietary data was self-reported which under-reports food intake, particularly fat consumption. Dietary data and blood samples were only collected once at the start of the study. Using self-reported data in such an important study is irresponsible and only collecting the data once is not going to provide valuable information.
- Regional variations in countries were not considered. There is a wide variation in diets of India and China. Variations in the regional diets of India are examined later.
- The role of poverty, disease and undernourishment has not been adequately taken into account. This is also examined in more detail later.

The study authors did note that: ⁷

While high-carbohydrate and low-fat diets might be a proxy for poverty or access to health care, all of our models adjusted for education and study centre (which tracks with country income and urban or rural location) and would be expected to account for differences in socioeconomic factors across intake categories.

Despite the assurances that access to health care and education was taken into account, more than a cursory glance at the data shows that it was far from adequate.

Whilst the authors of the PURE Study noted that **there was no association between total carbohydrate intake and heart attacks and stroke**, their conclusion was:

Higher fruit, vegetable, and legume consumption was associated with a lower risk of non-cardiovascular, and total mortality. Benefits appear to be maximum for both non-cardiovascular mortality and total mortality at three to four servings per day (equivalent to 375-500 g/day)

The people with the highest VFL intake were also smoking less, performed more physical activity, had a higher education level, a much better income and access to a much better health-care system.

Using multivariable analysis attempts to determine which factor is the most relevant in determining the observed lower total mortality that was associated with the VFL intake. The authors determined that having more than 3 - 4 servings of VFL is really not beneficial and that the other factors were more important. This is a failure of multivariate analysis - not a failure of VFL intake to provide demonstrable health benefits.

Regional Variations were not Considered

India is divided into six dietary regions. Even within these regions there are significant variations in the consumption of rice, wheat, millet, animal products, dairy, added oils, sugar, fish, fruit and vegetables.

In the north-east, Jammu and Kashmir in the north-west, vegan diets are virtually non-existent, whereas in Gujarat in the 4.9% are consume no animal products. Despite its reputation for a healthy, vegetarian diet, Indian diets are frequently high in fat, sugar, dairy and meat.

In rural Orissa, 4% of the energy is obtained from added oils whereas in Gujarat it is 13%.

Role of Infections Diseases and Health Care

The role of infectious disease, adequate health care and nutrition was not adequately taken into account. *Helicobacter pylori* is a gastric pathogen that colonises approximately 50% of the world's population. Infection with *H. pylori* is the strongest known risk factor for gastric cancer, which is the second leading cause of cancer-related deaths worldwide.⁸

How can the impact of *Helicobacter pylori* on a European population be compared to that of Bangladesh, India, China and Pakistan?

Country	Region	Income	Prevalence <i>H. pylori</i>
China	China	Middle	56.00%
India	South Asia	Low	63.00%
Pakistan	South Asia	Low	81.00%
Malaysia	SE Asia	Middle	29.00%
Denmark	Europe	High	22.00%

Sponsors

There is a very long list of sponsors including pharmaceutical companies – all anxious to provide medications especially since they can now claim that the link between diet and heart disease is unproven.

Conclusions

The conclusions of this study were:

Consistent with most data, but in contrast to dietary guidelines, we found fats, including saturated fatty acids, are not harmful and diets high in carbohydrate have adverse effects on total mortality. We did not observe any detrimental effect of higher fat intake on cardiovascular events.

Current guidelines recommend a low fat diet (<30% of energy) and limiting saturated fatty acids to less than 10% of energy intake by replacing them with unsaturated fatty acids. In conclusion, we found that a high carbohydrate intake was associated with an adverse impact on total mortality, whereas fats including saturated and unsaturated fatty acids were associated with lower risk of total mortality and stroke.

Diets of less than 30% energy from fat is not a low-fat diet. It is only slightly less than the US and Canadian average and median rate of 33% and is not nearly low enough to have any impact on health indicators.

Far too many nutrition researchers have a mistaken view that the health benefits of a diet

can be determined by the percentage intake of the macronutrient – fats, carbohydrates and protein.

The above conclusions are inconsistent with the PURE Study's own results that high Vegetable, Fruit and Legume intake is associated with a lower mortality rate and lower rate of cardiovascular events.

Benefits of Low-Fat, High-Carbohydrate and Plant-based Diets

Epidemiological studies, intervention trials, observational studies dating back to the 1950s show that low-fat, high-carbohydrate diets based on mostly on plants result in reduced cardiovascular mortality rates. Below are several examples.

Intervention Studies

A number of researchers studied the relationship of saturated fat to serum cholesterol during the 1950s. J Groen, LW Kinsell, EH Ahrens, A Keys, JM Beveridge and B Bronte-Stewart replaced saturated fats in the diet with polyunsaturated fats. All other components of the diet remained the same and the total fat content of the diet did not change.

When the unsaturated fats, such as corn or safflower oil, were replaced by the saturated fats of butter, lard, or coconut oil, the serum cholesterol rose. The serum cholesterol fell when the polyunsaturated fats were reintroduced. The experiments were repeated, and whilst there was variability with the amount of change for different individuals, the results were consistent for each individual. The changes occurred rapidly within one or two weeks. Ahrens's study kept the total fats at 40%, which was the average fat intake of the US at that time.⁹

Observation Studies

In 1947, Keys commenced the Minnesota Business and Professional Men Study to determine why apparently healthy middle-age men were dying from heart attacks. A number of variables were examined, with serum cholesterol being the most significant variable.¹⁰

In 1951, Keys was working at Oxford when the Food and Agriculture Organization asked him to chair their first conference on nutrition in Rome. He states, "The conferees talked only about nutritional deficiencies". When he asked about the new epidemic of coronary heart disease, Gino Bergami, Professor of Physiology at the University of Naples, said "coronary heart disease was no problem in Naples".¹¹

In 1952, Keys and his wife Margaret visited Naples. Margaret measured serum cholesterol concentrations and found them to be very low except among members of the Rotary Club.

Heart attacks were rare except amongst the rich whose diet included daily servings of meat. He obtained similar results in studies in Madrid.¹²

In 1955, Brian Bronte-Stewart, John Block (professor of medicine at University of Cape Town), Ancel and Margaret Keys and colleagues published a paper examining serum cholesterol, diet, income and cardiovascular mortality in Europeans, “Colored” and Bantu groups in Cape Town.¹³

Heart disease for Europeans was more than twice that of Cape Coloured and among Bantu it was “exceedingly rare as a cause of death”. This was the first study to show that the increase in LDL cholesterol was related to the consumption of animal fats.

In 1958, Keys and his colleagues published a paper examining serum cholesterol, diet and cardiovascular disease in Japanese living in Japan, Hawaii and Los Angeles. In Japan, “heart disease is rare, in Hawaii, where it is fairly common but less so than among local Caucasians, and in California, where the local Japanese are similar to the local Caucasians in regard to the frequency of the disease. In middle age, coronary heart disease is at least 10 times as common in the United States as in Japan.”¹⁴

North Karelia Project

The *Seven Countries Study* highlighted the high death rate, particularly from heart disease, in North Karelia and Finland. North Karelia is an inland region in Eastern Finland that borders Russia.

The North Karelia Project is documented in a 300-page document produced by Finland’s National Institute for Health and Welfare (THL), in collaboration with the North Karelia Project Foundation.¹⁵

In 1973, Finland had a highest country death rate for men from cardiac heart disease and North Karelia had the highest rate in Finland.

By 2007, the heart disease death rate for men dropped by 80%. Saturated fat intake decreased from 22% of dietary energy intake to 13% and total fat from 38% to 31-32%.

Over the period from 1971 to 2006, life expectancy at birth rose 8.2 years for males and 7.0 years for females.

As David Katz commented, the real conclusion from the PURE Study is: ¹⁶

Very poor people with barely anything to eat get sick and die more often than affluent people with access to both ample diets, and hospitals.

The above concerns preclude the study from serious consideration.

Footnotes

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