

Multiple Risk Factor Intervention Trial Clinical Center Laboratory of Physiological Hygiene School of Public Health Stadium Gate 27 Minneapolis, Minnesota 55455

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November 20, 1975

MEMORANDUM

TO: MRFIT Interventionists, which may be shown and read to and discussed with MRFIT participants

FROM: Henry Blackburn

A study reported this week at the American Heart Association meetings by Dr. Ivan Frantz at the University of Minnesota gives the results of a single factor (in contrast to multifactor) short term (not long term) clinical trial in mental disease patients (not high risk persons). As we have discussed at the MRFIT Orientation and elsewhere, it would be difficult to demonstrate a significant effect of lowering a single risk factor without having a huge number of participants (probably on the order of 40-50,000) followed many years (on the order of 5-10 years). The population studies which show the important differences in the heart attack risk associated with differences in diet are based of course on lifetime natural experiments.

It was important to attempt to reproduce the natural experiment, even for a short time and this is what Dr. Frantz' study did. If that study had been responsibly reported it would have indicated that there was an apparent reduction in coronary disease rates in individuals under age 50. But other serious problems in the study include that individuals in the mental hospitals during this period were relatively free to go home on weekends, free to leave the hospital, at which time their diet was not controlled. The average exposure of people to the diet was only a couple of years. It would be unreasonable indeed to expect any significant effect on the basic disease process in a short time and with this exposure.

The hypothesis that MRFIT is testing is that in individuals who have multiple mild or moderately elevated risk characteristics (including serum cholesterol) multiple interventions may reduce risk. The Frantz study did not involve high risk people, but mental patients actually at low risk.

Thus, the Minnesota mental hospitals study in no way "casts doubt on the link between heart attack and cholesterol". That link is strongly and firmly demonstrated in the Seven Countries study and the other studies we have outlined for you. Risk of heart attack is <u>directly</u> related to level of cholesterol and consequently it is important that the level of cholesterol be modified. This hospital study was simply of inadequate duration and design. It would have indeed been exciting if the results had been dramatic, but it casts no doubt on the general relationship.

(cont...)

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In a more responsible report by Mr. Slovut, a Minneapolis STAR writer, the results are given more accurately. He indicated that the result was positive in younger people and he indicated that the subjects had "normal cholesterol" and risk rather than high risk.